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(Original Signature of Member)

107TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. FLETCHER (for himself, Mr. PETERSON of Minnesota, Mrs. JOHNSON of Connecticut, and Mr. BURR of North Carolina) introduced the following bill; which was referred to the Committee on _____

A BILL

To protect consumers in managed care plans and in other health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Patients' Bill of Rights Act of 2001''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SEC. 101. ACCESS TO EMERGENCY MEDICAL CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION.—The term ''emergency medical condition'' means—

(i) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act; and

(ii) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term ''emergency services'' means—

(i) with respect to an emergency medical condition described in subparagraph (A)(i)—

(I) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(II) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

(ii) with respect to an emergency medical condition described in subparagraph (A)(ii), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

(C) STABILIZE.—The term ''to stabilize'', with respect to an emergency medical condition, has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—If benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, with respect to services that are provided as maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant or beneficiary other than through a participating health

care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage provided by a health insurance issuer, provides any benefits with respect to ambulance services and emergency services, the plan or issuer shall cover emergency ambulance services (as defined in paragraph (2))) furnished under the plan or coverage under the same conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ''emergency ambulance services'' means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan or coverage pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS.

(a) REQUIREMENT.—If a group health plan provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits (including physician pathology services) for which coverage is otherwise so limited. Such option shall be made available to the participant at the time

of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term ''point-of-service coverage'' means, with respect to benefits (including physician pathology services) covered under a group health plan, coverage of such benefits when provided by a nonparticipating health care professional.

(c) SMALL EMPLOYER EXEMPTION.—

(1) IN GENERAL.—This section shall not apply to any group health plan with respect to a small employer.

(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term ''small employer'' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 25 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring coverage for benefits for a particular type of health care professional;

(2) as preventing a group health plan from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

(3) to require that a group health plan include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

SEC. 103. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, and health insurance coverage offered by a health insurance issuer, described in subsection (b) may not require authorization or referral by the primary care provider described in sub-

section (b)(2) in the case of a female participant or beneficiary who seeks coverage for obstetric or gynecological care provided by a participating physician or by a participating health care professional who specializes in obstetrics or gynecology and is operating within State licensure and scope of practice laws.

(2) OBSTETRIC AND GYNECOLOGICAL CARE.—Such a plan or issuer shall treat the provision of obstetric and gynecological care, and the ordering of related obstetric and gynecological items and services, pursuant to the direct access described under paragraph (1), by a participating physician or other health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(b) APPLICATION OF SECTION.—A group health plan, or health insurance coverage offered by a health insurance issuer, described in this subsection is a plan or coverage that—

(1) provides coverage for obstetric or gynecological care; and

(2) requires the designation by a participant or beneficiary of a participating primary care provider other than a physician who specializes in obstetrics or gynecology.

(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require that a group health plan or health insurance issuer approve or provide coverage for—

(A) any items or services that are not covered under the terms and conditions of the group health plan or the health insurance coverage;

(B) any items or services that are not medically necessary and appropriate; or

(C) any items or services that are provided, ordered, or otherwise authorized under subsection (a)(2) by a physician or other health care professional unless such items or services are related to obstetric or gynecological care;

(2) to preclude a group health plan or health insurance issuer from requiring that the physician or health care professional described in subsection (a) notify the designated primary care professional or case manager of treatment decisions in accordance with a process implemented by the plan, except that the group health plan or issuer shall not impose such a notification requirement on the participant or beneficiary involved in the treatment decision; or

(3) to preclude a group health plan or health insurance issuer from requiring authorization, including prior authorization, for items and services (other than routine items and services) from the physician or health care professional described in subsection (a) who specializes in obstetrics and gynecology if the designated primary care provider of the participant or beneficiary would otherwise be required to obtain authorization for such items or services.

For purposes of paragraph (3), routine items and services includes annual, prenatal, and perinatal examinations.

SEC. 104. ACCESS TO PEDIATRIC CARE.

(a) PEDIATRIC CARE.—If a group health plan, and a health insurance issuer that offers health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider for a child of such participant, beneficiary, or enrollee, the plan or issuer shall permit the participant, beneficiary, or enrollee to designate a physician who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(b) RULES OF CONSTRUCTION.—With respect to the child of a participant, beneficiary, or enrollee, nothing in subsection (a) shall be construed to—

(1) require that the participant, beneficiary, or enrollee obtain prior authorization or a referral from a primary care provider in order to obtain pediatric care from a health care professional other than a physician if the provision of pediatric care by such professional is permitted by

the plan or issuer and consistent with State licensure, credentialing, and scope of practice laws and regulations; or

(2) preclude the participant, beneficiary, or enrollee from designating a health care professional other than a physician as a primary care provider for the child if such designation is permitted by the plan or issuer and the treatment by such professional is consistent with State licensure, credentialing, and scope of practice laws.

SEC. 105. TIMELY ACCESS TO SPECIALISTS.

(a) TIMELY ACCESS.—

(1) IN GENERAL.—A group health plan, or a health insurance issuer offering health insurance coverage, shall ensure that participants and beneficiaries receive timely coverage for access to specialists with respect to the medical condition of the participant or beneficiary, when such specialty care is a covered benefit under the plan or coverage.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the coverage under a group health plan or health insurance coverage of benefits or services;

(B) to prohibit a plan or issuer from including providers in the network only to the extent necessary to meet the needs of the plan's participants and beneficiaries;

(C) to prohibit a plan or issuer from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(D) to override any State licensure or scope-of-practice law.

(3) ACCESS TO CERTAIN PROVIDERS.—

(A) PARTICIPATING PROVIDERS.—Nothing in this section shall be construed to prohibit a group health plan or health insurance issuer from requiring that a

participant or beneficiary obtain specialty care from a participating specialist.

(B) NONPARTICIPATING PROVIDERS.—

(i) IN GENERAL.—With respect to specialty care under this section, if a group health plan or health insurance issuer determines that a participating specialist is not available to provide such care to the participant or beneficiary, the plan or issuer shall provide for coverage of such care by a nonparticipating specialist.

(ii) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a group health plan or health insurance issuer refers a participant or beneficiary to a nonparticipating specialist pursuant to clause (i), such specialty care shall be provided at no additional cost to the participant or beneficiary beyond what the participant or beneficiary would otherwise pay for such specialty care if provided by a participating specialist.

(b) REFERRALS.—

(1) AUTHORIZATION.—Nothing in this section shall be construed to prohibit a group health plan or health insurance issuer from requiring an authorization in order to obtain coverage for specialty services so long as such authorization is for an appropriate duration or number of referrals.

(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

(A) IN GENERAL.—A group health plan, or a health insurance issuer offering health insurance coverage, shall permit a participant or beneficiary who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the

terms of a treatment plan referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ''ongoing special condition'' means a condition or disease that—

(i) is life-threatening, degenerative, or disabling; and

(ii) requires specialized medical care over a prolonged period of time.

(c) TREATMENT PLANS.—

(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan or health insurance issuer from requiring that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

(A) developed by the specialist, in consultation with the case manager or primary care provider, and the participant or beneficiary;

(B) approved by the plan or issuer in a timely manner if the plan or issuer requires such approval; and

(C) in accordance with the applicable quality assurance and utilization review standards of the plan or issuer.

(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a group health plan or health insurance issuer from requiring the specialist to provide the plan or issuer with regular updates on the specialty care provided, as well as all other necessary medical information.

(d) SPECIALIST DEFINED.—For purposes of this section, the term ''specialist'' means, with respect to the medical condition of the participant or beneficiary, a physician (including an allopathic or osteopathic physician) or health care professional who is appropriately credentialed or licensed in 1 or more States, who has adequate expertise, appropriate training and

experience, and routinely treats the diagnosis or condition of the participant or beneficiary.

SEC. 106. CONTINUITY OF CARE.

(a) TERMINATION OF PROVIDER.—If a contract between a group health plan, and a health insurance issuer that offers health insurance coverage, as appropriate, and a treating health care provider is terminated (as defined in paragraph (e)(4)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such plan or coverage, and an individual who is a participant, beneficiary or enrollee under such plan or coverage is undergoing an active course of treatment for a serious and complex condition, institutional care, pregnancy, or terminal illness from the provider at the time the plan or issuer receives or provides notice of such termination, the plan or issuer shall—

(1) notify the individual, or arrange to have the individual notified pursuant to subsection (d)(2), on a timely basis of such termination;

(2) provide the individual with an opportunity to notify the plan or issuer of the individual's need for transitional care; and

(3) subject to subsection (c), permit the individual to elect to continue to be covered with respect to the active course of treatment with the provider's consent during a transitional period (as provided for under subsection (b)).

Nothing in this section shall be construed as preventing a plan or issuer from providing the notice under paragraph (1) before the effective date of the provider's termination.

(b) TRANSITIONAL PERIOD.—

(1) SERIOUS AND COMPLEX CONDITIONS.—The transitional period under this section with respect to a serious and complex condition shall extend for up to 90 days from the date of the notice described in subsection (a)(1) of the provider's termination.

(2) INSTITUTIONAL OR INPATIENT CARE.—

(A) IN GENERAL.—The transitional period under this section for institutional or non-elective inpatient care from a provider shall extend until the earlier of—

(i) the expiration of the 90-day period beginning on the date on which the notice described in subsection (a)(1) of the provider's termination is provided; or

(ii) the date of discharge of the individual from such care or the termination of the period of institutionalization.

(B) SCHEDULED CARE.—The 90 day limitation described in subparagraph (A)(i) shall include post-surgical follow-up care relating to non-elective surgery that has been scheduled before the date of the notice of the termination of the provider under subsection (a)(1).

(3) PREGNANCY.—If—

(A) a participant, beneficiary, or enrollee was pregnant at the time of a provider's termination of participation; and

(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation; and

(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall extend for the remainder of the individual's life for care that is directly related to the treatment of the terminal illness.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan, and a health insurance issuer that offers health in-

surance coverage, may condition coverage of continued treatment by a provider under this section upon the provider agreeing, in advance in writing, to the following:

(1) The treating health care provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the plan or issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in this section had not been terminated (or, if applicable, at the cost-sharing applicable under the replacement plan).

(2) The treating health care provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The treating health care provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider; or

(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan or health insurance issuer from requiring that the health care provider—

(A) notify participants, beneficiaries, or enrollees of their rights under this section; or

(B) provide the plan or issuer with the name of each participant, beneficiary, or enrollee who the provider believes is eligible for transitional care under this section.

(e) DEFINITIONS.—In this section:

(1) CONTRACT.—The term ''contract between a group health plan, and a health insurance issuer that offers health insurance coverage, and a treating health care provider'' shall include a contract between such a plan or issuer and an organized network of providers.

(2) HEALTH CARE PROVIDER.—The term ''health care provider'' or ''provider'' means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(3) SERIOUS AND COMPLEX CONDITION.—The term ''serious and complex condition'' means, with respect to a participant, beneficiary, or enrollee under the plan or coverage, a condition that is medically determinable and—

(A) in the case of an acute illness, is a condition serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

(B) in the case of a chronic illness or condition, is an illness or condition that—

(i) is complex and difficult to manage;

(ii) is disabling or life- threatening; and

(iii) requires—

(I) frequent monitoring over a prolonged period of time and requires substantial ongoing specialized medical care; or

(II) frequent ongoing specialized medical care across a variety of domains of care.

(4) TERMINATED.—The term ''terminated'' includes, with respect to a contract (as defined in paragraph (1)), the expiration or nonrenewal of the contract with the provider by the group health plan or health insurance issuer, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

SEC. 107. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

(a) IN GENERAL.—Subject to subsection (b), a group health plan, and a health insurance issuer that offers health insurance coverage, (in relation to a participant, beneficiary, or enrollee) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the participant, beneficiary, or enrollee or medical care or treatment for the condition or disease of the participant, beneficiary, or enrollee, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan, or a health insurance issuer that offers health insurance coverage, to provide specific benefits under the terms of such plan or coverage.

(c) NULLIFICATION.—Any contract provision that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

SEC. 108. PATIENT ACCESS TO PRESCRIPTION DRUGS.

(a) IN GENERAL.—To the extent that a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage for benefits with respect to prescrip-

tion drugs, and limits such coverage to drugs included in a formulary, the plan or issuer shall—

(1) ensure the establishment of a pharmaceutical and therapeutic committee that develops the formulary, the majority of the members of which must be individuals who are physicians or pharmacists; and

(2) in accordance with the applicable quality assurance and utilization review standards of the plan or issuer, provide for exceptions from the formulary limitation when—

(A) the prescribing physician (or the prescribing health care professional) requests such an exception;

(B) the drugs on the formulary within a therapeutic class—

(i) are (or are likely to be) not as effective for the specific patient as the non-formulary drug, or

(ii) in comparison with the non-formulary drug, have (or are likely to have) greater significant adverse side-effects for the specific patient; and

(C) the non-formulary drug is medically necessary and appropriate for the specific patient.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from excluding coverage for a specific drug or class of drugs if such drugs or class of drugs is expressly excluded under the terms and conditions of the plan or coverage.

(c) INFORMATION DISCLOSURE REQUIRED.—Disclosure to patients and physicians of information on formulary restrictions is required under subsections (a), (b)(10), and (c)(2) of section 121(a).

SEC. 109. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, and a health insurance issuer that offers health insurance cov-

erage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the participant's, beneficiaries, or enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of this section, routine patient costs do not include costs of items and services (including transportation, tests, measurements, and procedures) that are provided primarily for the purpose of the clinical trial involved or that otherwise are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ''qualified individual'' means an individual who is a participant or beneficiary in a group health plan or an enrollee in health insurance coverage and who meets all the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan, and a health insurance issuer offering health insurance coverage, shall provide for payment for routine patient costs consistent with subsection (a)(2).

(2) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ''approved clinical trial'' means a clinical research study or clinical investigation approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) The Food and Drug Administration, but only with respect to cancer clinical research studies or cancer clinical investigations.

(D) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to preclude a plan or issuer from offering coverage that is broader than the coverage required under this section with respect to clinical trials.

(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle

B of title I of the Employee Retirement Income Security Act of 1974.

(g) STUDY AND REPORT.—

(1) STUDY.—The Secretary shall study the impact on group health plans and health insurance issuers for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved clinical trial program.

(2) REPORT TO CONGRESS.—Not later than January 1, 2006, the Secretary shall submit a report to Congress that contains an assessment of—

(A) any incremental cost to group health plans and health insurance issuers resulting from the provisions of this section;

(B) a projection of expenditures to such plans and issuers resulting from this section; and

(C) any impact on premiums resulting from this section.

SEC. 110. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

(a) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(b) CONSTRUCTION.—Subsection (a) shall not be construed—

(1) as requiring the coverage under a group health plan or health insurance coverage of a particular benefit or service or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law;

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or coverage; or

(4) as prohibiting a family practice physician with appropriate expertise from providing pediatric, obstetric, gynecological, or other appropriate care.

SEC. 111. GENERALLY APPLICABLE PROVISION.

Notwithstanding section 102, in the case of a group health plan, and a health insurance issuer that offers health insurance coverage, that provides benefits under 2 or more coverage options, the requirements of this subtitle shall apply separately with respect to each coverage option.

Subtitle B—Right to Information About Plans and Providers

SEC. 121. HEALTH PLAN INFORMATION.

(a) REQUIREMENT.—

(1) DISCLOSURE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall provide for the disclosure of the information described in subsection (b) to participants, beneficiaries, and enrollees—

(i) at the time of the initial enrollment of the participant, beneficiary, or enrollee under the plan or coverage;

(ii) on an annual basis after enrollment—

(I) in conjunction with the election period of the plan or coverage if the plan or coverage has such an election period; or

(II) in the case of a plan or coverage that does not have an election period, in conjunction with the beginning of the plan or coverage year; and

(iii) in the case of any material reduction to the benefits or information described in paragraphs (1), (2) and (3) of subsection (b), in the form of a summary notice provided not later than the date on which the reduction takes effect.

(B) PARTICIPANTS, BENEFICIARIES, OR ENROLLEES.—The disclosure required under subparagraph (A) shall be provided—

(i)(I) jointly to each participant and beneficiary who reside at the same address; or

(II) in the case of a beneficiary who does not reside at the same address as the participant, separately to the participant and such beneficiary; and

(ii) to each enrollee.

(2) DISCLOSURE OF PRESCRIPTION DRUG INFORMATION TO PARTICIPATING PHYSICIANS.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall provide for the disclosure of the information described in subsection (b)(10) and in subsection (c)(2) to participating physicians upon request.

(3) PROVISION OF INFORMATION.—Information shall be provided to participants, beneficiaries, and enrollees under this section at the last known address maintained by the plan or issuer with respect to such participants, beneficiaries, or enrollees, to the extent that such information is provided to participants, beneficiaries, or enrollees via the United States Postal Service or other private delivery service.

(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a group health plan sponsor and health insurance issuer from entering into an agreement under which either the plan sponsor or the issuer agrees to assume responsibility for compliance with the requirements of this section, in whole or in part, and the party delegating such responsibility is released from liability for compliance with the requirements that are assumed

by the other party, to the extent the party delegating such responsibility did not cause such noncompliance.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each option available under the group health plan and health insurance coverage the following:

(1) BENEFITS.—A description of the covered benefits, including—

(A) any in- and out-of-network benefits;

(B) specific preventative services covered under the plan or coverage if such services are covered;

(C) any benefit limitations, including any annual or lifetime benefit limits and any monetary limits or limits on the number of visits, days, or services, and any specific coverage exclusions; and

(D) any definition of medical necessity used in making coverage determinations by the plan, issuer, or claims administrator.

(2) COST SHARING.—A description of any cost-sharing requirements, including—

(A) any premiums, deductibles, coinsurance, copayment amounts, and liability for balance billing above any reasonable and customary charges, for which the participant, beneficiary, or enrollee will be responsible under each option available under the plan;

(B) any maximum out-of-pocket expense for which the participant, beneficiary, or enrollee may be liable;

(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

(D) any additional cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or precertification.

(3) SERVICE AREA.—A description of the plan or issuer's service area, including the provision of any out-of-area coverage.

(4) PARTICIPATING PROVIDERS.—A directory of participating providers (to the extent a plan or issuer provides coverage through a network of providers) that includes, at a minimum, the name, address, and telephone number of each participating provider, and information about how to inquire whether a participating provider is currently accepting new patients.

(5) CHOICE OF PRIMARY CARE PROVIDER.—A description of any requirements and procedures to be used by participants, beneficiaries, and enrollees in selecting, accessing, or changing their primary care provider, including providers both within and outside of the network (if the plan or issuer permits out-of-network services), and the right to select a pediatrician as a primary care provider under section 104 for a participant, beneficiary, or enrollee who is a child if such section applies.

(6) PREAUTHORIZATION REQUIREMENTS.—A description of the requirements and procedures to be used to obtain preauthorization for health services, if such preauthorization is required.

(7) EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS.—A description of the process for determining whether a particular item, service, or treatment is considered experimental or investigational, and the circumstances under which such treatments are covered by the plan or issuer.

(8) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants, beneficiaries, and enrollees in accessing specialty care and obtaining referrals to participating and nonparticipating specialists, including the right to timely coverage for access to specialists care under section 105 if such section applies.

(9) CLINICAL TRIALS.—A description the circumstances and conditions under which participation in clinical trials is covered under the terms and conditions of the plan or coverage, and the right to obtain coverage for

approved cancer clinical trials under section 109 if such section applies.

(10) PRESCRIPTION DRUGS.—To the extent the plan or issuer provides coverage for prescription drugs, a statement of whether such coverage is limited to drugs included in a formulary, a description of any provisions and cost-sharing required for obtaining on- and off-formulary medications, and a description of the rights of participants, beneficiaries, and enrollees in obtaining access to access to prescription drugs under section 107 if such section applies.

(11) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant, beneficiary, or enrollee to obtain emergency services under the prudent layperson standard under section 101, if such section applies, and any educational information that the plan or issuer may provide regarding the appropriate use of emergency services.

(12) CLAIMS AND APPEALS.—A description of the plan or issuer's rules and procedures pertaining to claims and appeals, a description of the rights of participants, beneficiaries, or enrollees under sections 503, 503A and 503B of the Employee Retirement Income Security Act of 1974 (or sections 2707(b) and 2753(b) of the Public Health Service with respect to non-Federal governmental plans and individual health insurance coverage) in obtaining covered benefits, filing a claim for benefits, and appealing coverage determinations internally and externally (including telephone numbers and mailing addresses of the appropriate authority), and a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974.

(13) ADVANCE DIRECTIVES AND ORGAN DONATION.—A description of procedures for advance directives and organ donation decisions if the plan or issuer maintains such procedures.

(14) INFORMATION ON PLANS AND ISSUERS.—The name, mailing address, and telephone number or numbers of the plan administrator and the issuer to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage benefits and services, payment of a claim, or authorization for services and treatment. The name of the designated decisionmaker (or decisionmakers) appointed under section 502(n)(2) of the Employee Retirement Income Security Act of 1974 for purposes of making final determinations under section 503A of such Act and approving coverage pursuant to the written determination of an independent medical reviewer under section 503B of such Act. Notice of whether the benefits under the plan are provided under a contract or policy of insurance issued by an issuer, or whether benefits are provided directly by the plan sponsor who bears the insurance risk.

(15) TRANSLATION SERVICES.—A summary description of any translation or interpretation services (including the availability of printed information in languages other than English, audio tapes, or information in Braille) that are available for non-English speakers and participants, beneficiaries, and enrollees with communication disabilities and a description of how to access these items or services.

(16) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes available to participants, beneficiaries, and enrollees.

(17) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and enrollees that are established by this Act (excluding those described in paragraphs (1) through (16)) if such rights apply. The description required under this paragraph may be combined with the notices required under sections 711(d), 713(b), or 606(a)(1) of the Employee Retirement Income Security Act

of 1974, and with any other notice provision that the Secretary determines may be combined.

(18) COMPENSATION METHODS.—A summary description of the methods (including capitation, fee-for-service, salary, withholds, bonuses, bundled payments, per diem, or a combination thereof) used for compensating participating health care professionals (including primary care providers and specialists) and facilities in connection with the provision of health care under the plan or coverage. The requirement of this paragraph shall not be construed as requiring plans or issuers to provide information concerning proprietary payment methodology.

(19) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described in subsection (c), and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant, beneficiary, or enrollees shall include for each option available under a group health plan and health insurance coverage the following:

(1) STATUS OF PROVIDERS.—The State licensure status of the plan or issuer's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

(2) PRESCRIPTION DRUGS.—Information about whether a specific prescription medication is included in the formulary of the plan or issuer, if the plan or issuer uses a defined formulary.

(3) EXTERNAL APPEALS INFORMATION.—Aggregate information on the number and outcomes of external medical reviews, relative to the sample size (such as the number of covered lives) determined for the plan or issuer's book of business.

(d) MANNER OF DISCLOSURE.—The information described in this section shall be disclosed in an accessible medium and format that is calculated to be understood by the average participant.

(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health plan; and

(2) complying with the provisions of this section by providing information in brochures, through the Internet or other electronic media, or through other similar means, so long as participants, beneficiaries, and enrollees are provided with an opportunity to request that informational materials be provided in printed form.

(f) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

(g) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services or the Secretary of Labor (as appropriate) may assess a civil monetary penalty against the administrator of a plan or issuer in connection with the failure of the plan or issuer to comply with the requirements of this section.

(2) AMOUNT OF PENALTY.—The amount of the penalty to be imposed under paragraph (1) shall not exceed $100 for each day for each participant, beneficiary, or enrollee with respect to which the failure to comply with the requirements of this section occurs.

(3) FAILURE DEFINED.—For purposes of this subsection, a plan or issuer shall have failed to comply with

the requirements of this section with respect to a participant, beneficiary, or enrollee if the plan or issuer failed or refused to comply with the requirements of this section within 30 days—

(A) of the date described in subsection (a)(1)(A)(i);

(B) of the date described in subsection (a)(1)(A)(ii); or

(C) of the date on which additional information was requested under subsection (c).

(h) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''section 711 and section 121 of the Patients' Bill of Rights Act of 2001''.

(2) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by striking ''733(a)(1))'' and inserting ''733(a)(1)), except with respect to the requirements of section 121 of the Patients' Bill of Rights Act of 2001''.

SEC. 122. STUDY ON THE EFFECT OF PHYSICIAN COMPENSATION METHODS.

(a) STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the conduct of a study in accordance with this section, to be submitted to the Secretary and the Secretary of Labor as provided for in paragraph (4).

(2) MATTERS TO BE STUDIED.—The study under paragraph (1) shall include—

(A) a study, including a survey if necessary, of physician compensation arrangements that are utilized in employer-sponsored group health plans (including group health plans sponsored by government and non-government employers) and commercial health insurance products, including—

(i) all types of compensation arrangements, including financial incentive and risk sharing arrangements and arrangements that do not contain such incentives and risk sharing, that reflect the complexity of organizational relationships between health plans and physicians;

(ii) arrangements that are based on factors such as utilization management, cost control, quality improvement, and patient or enrollee satisfaction; and

(iii) arrangements between the plan or issuer and provider, as well as down-stream arrangements between providers and sub-contracted providers;

(B) an analysis of the effect of such differing arrangements on physician behavior with respect to the provision of medical care to patients, including whether and how such arrangements affect the quality of patient care and the ability of physicians to provide care that is medically necessary and appropriate.

(3) STUDY DESIGN.—The Secretary shall consult with the Director of the Agency for Healthcare Research and Quality in preparing the scope of work and study design with respect to the contract under paragraph (1).

(4) REPORT.—Not later than 24 months after the date of enactment of this Act, the Secretary shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

(b) RESEARCH.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall conduct and support research to develop scientific evidence regarding the effects of differing physician compensation methods on physician behavior with respect to the provision of medical care to patients, particularly issues relating to the quality of patient care and whether patients receive medically necessary and appropriate care.

(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

Subtitle C—Right to Hold Health Plans Accountable

SEC. 131. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by inserting after section 503 (29 U.S.C. 1133) the following:

"SEC. 503A. CLAIMS AND INTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

"(a) INITIAL CLAIM FOR BENEFITS UNDER GROUP HEALTH PLANS.—

"(1) PROCEDURES.—

"(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall ensure that procedures are in place for—

"(i) making a determination on an initial claim for benefits by a participant or beneficiary (or authorized representative) regarding payment or coverage for items or services under the terms and conditions of the plan or coverage involved, including any cost-sharing amount that the participant or beneficiary is required to pay with respect to such claim for benefits; and

"(ii) notifying a participant or beneficiary (or authorized representative) and the treating health care professional involved regarding a determination on an initial claim for benefits made under the terms and conditions of the plan or coverage, including any cost-sharing amounts that the participant or beneficiary may be required to make with respect to such claim for benefits, and of the right of the participant or beneficiary to an internal appeal under subsection (b).

"(B) ACCESS TO INFORMATION.—With respect to an initial claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the claim, not later than 5 days after the date on which the claim is filed or to meet the applicable timelines under clauses (ii) and (iii) of paragraph (2)(A).

"(C) ORAL REQUESTS.—In the case of a claim for benefits involving an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

"(2) TIMELINE FOR MAKING DETERMINATIONS.—

"(A) PRIOR AUTHORIZATION DETERMINATION.—

"(i) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a prior authorization determination on a claim for benefits is made within 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the request for prior authorization, but in no case shall such determination be made later than 21 days after the receipt of the claim for benefits.

"(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, and a health insurance issuer that offers health insurance

coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on a claim for benefits described in such clause when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made within 72 hours after a request is received by the plan or issuer under this clause.

"(iii) CONCURRENT DETERMINATIONS.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the claim for benefits.

"(B) RETROSPECTIVE DETERMINATION.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on a claim for benefits is made within 30 days of the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the claim, but in no case shall such determination be made later than 60 days after the receipt of the claim for benefits.

"(3) NOTICE OF A DENIAL OF A CLAIM FOR BENEFITS.—Written notice of a denial made under an initial claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating

health care professional not later than 2 days after the determination (or within the 72-hour or 24-hour period referred to in clauses (ii) and (iii) of paragraph (2)(A) if applicable).

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—The written notice of a denial of a claim for benefits determination under paragraph (3) shall include—

"(A) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in making the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

"(B) the procedures for obtaining additional information concerning the determination; and

"(C) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (b).

"(b) INTERNAL APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS.—

"(1) RIGHT TO INTERNAL APPEAL.—

"(A) IN GENERAL.—A participant or beneficiary (or authorized representative) may appeal any denial of a claim for benefits under subsection (a) under the procedures described in this subsection.

"(B) TIME FOR APPEAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall ensure that a participant or beneficiary (or authorized representative) has a period of not less than 90 days beginning on the date of a denial of a claim for benefits under subsection (a) in which to appeal such denial under this subsection.

"(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on a claim for benefits under subsection (a) within the applicable timeline established for such a determination under such sub-

section shall be treated as a denial of a claim for benefits for purposes of proceeding to internal review under this subsection.

"(D) PLAN WAIVER OF INTERNAL REVIEW.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, may waive the internal review process under this subsection and permit a participant or beneficiary (or authorized representative) to proceed directly to external review under section 503B.

"(2) TIMELINES FOR MAKING DETERMINATIONS.—

"(A) ORAL REQUESTS.—In the case of an appeal of a denial of a claim for benefits under this subsection that involves an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may request such appeal orally, but a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

"(B) ACCESS TO INFORMATION.—With respect to an appeal of a denial of a claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the appeal, not later than 5 days after the date on which the request for the appeal is filed or to meet the applicable timelines under clauses (ii) and (iii) of subparagraph (C).

"(C) PRIOR AUTHORIZATION DETERMINATIONS.—

"(i) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a determination on an appeal of a denial of a claim

for benefits under this subsection is made within 14 days after the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal, but in no case shall such determination be made later than 21 days after the receipt of the request for the appeal.

''(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on an appeal of a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the request for such appeal is received by the plan or issuer under this clause.

''(iii) CONCURRENT DETERMINATIONS.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on an appeal of a denial of a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the request for appeal.

''(B) RETROSPECTIVE DETERMINATION.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group

health plan, shall maintain procedures to ensure that a retrospective determination on an appeal of a claim for benefits is made within 30 days of the date on which the plan or issuer receives necessary information that is reasonably required by the plan or issuer to make a determination on the appeal, but in no case shall such determination be made later than 60 days after the receipt of the request for the appeal.

''(3) CONDUCT OF REVIEW.—

''(A) IN GENERAL.—A review of a denial of a claim for benefits under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

''(B) REVIEW OF MEDICAL DETERMINATIONS BY PHYSICIANS.—A review of an appeal of a denial of a claim for benefits that is based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, or requires an evaluation of medical facts, shall be made by a physician with appropriate expertise, including pediatric expertise where necessary, to evaluate the relevant conditions, who was not involved in the initial determination.

''(4) NOTICE OF DETERMINATION.—

''(A) IN GENERAL.—Written notice of a determination made under an internal appeal of a denial of a claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating health care professional not later than 2 days after the completion of the review (or within the 72-hour or 24-hour period referred to in paragraph (2) if applicable).

''(B) FINAL DETERMINATION.—The determination by a plan or issuer under this subsection shall be treated as the final determination of the plan or issuer on a denial of a claim for benefits.

''(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on an appeal of a denial

of a claim for benefits under this subsection within the applicable timeline established for such a determination shall be treated as a final determination on an appeal of a denial of a claim for benefits for purposes of proceeding to external review under section 503B.

"(D) REQUIREMENTS OF NOTICE.—With respect to a determination made under this subsection, the notice described in subparagraph (A) shall include—

"(i) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in making the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

"(ii) the procedures for obtaining additional information concerning the determination; and

"(iii) notification of the right to an independent external review under section 503B and instructions on how to initiate such a review.

"(c) DEFINITIONS.—The definitions contained in section 503B(i) shall apply for purposes of this section.

"SEC. 503B. INDEPENDENT EXTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

"(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall provide in accordance with this section participants and beneficiaries (or authorized representatives) with access to an independent external review for any denial of a claim for benefits.

"(b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

"(1) TIME TO FILE.—A request for an independent external review under this section shall be filed with the plan or issuer not later than 90 days after the date on which the participant or beneficiary receives notice of the denial under section 503A(b)(4) or the date on which the

internal review is waived by the plan or issuer under section 503A(b)(1)(D).

"(2) FILING OF REQUEST.—

"(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, may—

"(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

"(ii) limit the filing of such a request to the participant or beneficiary involved (or an authorized representative);

"(iii) except if waived by the plan or issuer under section 503A(b)(1)(D), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 503A;

"(iv) except as provided in subparagraph (B)(ii), require payment of a filing fee to the plan or issuer of a sum that does not exceed $50; and

"(v) require that a request for review include the consent of the participant or beneficiary (or authorized representative) for the release of medical information or records of the participant or beneficiary to the qualified external review entity for purposes of conducting external review activities.

"(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

"(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. In such case a written confirmation of such request shall be made in a timely manner. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v).

"(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

"(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the Secretary) that the participant or beneficiary is indigent (as defined in such guidelines). In establishing guidelines under this subclause, the Secretary shall ensure that the guidelines relating to indigency are consistent with the poverty guidelines used by the Secretary of Health and Human Services under title XIX of the Social Security Act.

"(II) FEE NOT REQUIRED.—Payment of a filing fee shall not be required under subparagraph (A)(iv) if the plan or issuer waives the internal appeals process under section 503A(b)(1)(D).

"(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent external review is to reverse the denial which is the subject of the review.

"(IV) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A)(iv) shall be increased or decreased, for each calendar year that ends after December 31, 2002, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2002.

"(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

''(1) IN GENERAL.—Upon the filing of a request for independent external review with the group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, the plan or issuer shall refer such request to a qualified external review entity selected in accordance with this section.

''(2) ACCESS TO PLAN OR ISSUER AND HEALTH PROFESSIONAL INFORMATION.—With respect to an independent external review conducted under this section, the participant or beneficiary (or authorized representative), the plan or issuer, and the treating health care professional (if any) shall provide the external review entity with access to information requested by the external review entity that is necessary to conduct a review under this section, as determined by the entity, not later than 5 days after the date on which a request is referred to the qualified external review entity under paragraph (1), or earlier as determined appropriate by the entity to meet the applicable timelines under clauses (ii) and (iii) of subsection (e)(1)(A).

''(3) SCREENING OF REQUESTS BY QUALIFIED EXTERNAL REVIEW ENTITIES.—

''(A) IN GENERAL.—With respect to a request referred to a qualified external review entity under paragraph (1) relating to a denial of a claim for benefits, the entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

''(i) any of the conditions described in subsection (b)(2)(A) have not been met;

''(ii) the thresholds described in subparagraph (B) have not been met;

''(iii) the denial of the claim for benefits does not involve a medically reviewable determination under subsection (d)(2);

''(iv) the denial of the claim for benefits relates to a determination regarding whether an individual is a participant or beneficiary who is en-

rolled under the terms of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

"(v) the denial of the claim for benefits is a determination as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage unless the determination is a denial described in subsection (d)(2);

Upon making a determination that any of clauses (i) through (v) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eligible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (D).

"(B) THRESHOLDS.—

"(i) IN GENERAL.—The thresholds described in this subparagraph are that—

"(I) the total amount payable under the plan or coverage for the item or service that was the subject of such denial exceeds $100; or

"(II) a physician has asserted in writing that there is a significant risk of placing the life, health, or development of the participant or beneficiary in jeopardy if the denial of the claim for benefits is sustained.

"(ii) THRESHOLDS NOT APPLIED.—The thresholds described in this subparagraph shall not apply if the plan or issuer involved waives the internal appeals process with respect to the denial of a claim for benefits involved under section 503A(b)(1)(D).

"(C) PROCESS FOR MAKING DETERMINATIONS.—

"(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations under subpara-

graph (A), there shall be no deference given to determinations made by the plan or issuer under section 503A or the recommendation of a treating health care professional (if any).

"(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

"(D) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

"(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant or beneficiary (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

"(I) shall be written (and, in addition, may be provided orally) in a manner calculated to be understood by an average participant;

"(II) shall include the reasons for the determination; and

"(III) include any relevant terms and conditions of the plan or coverage.

"(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external review entity, and if required the independent medical reviewer, shall make a determination within the overall timeline that is applicable to the case under review as described in subsection (e), except that if the entity determines that a referral to an independent medical reviewer is not required, the entity shall provide notice of such determination to the participant

or beneficiary (or authorized representative) within 2 days of such determination.

"(d) INDEPENDENT MEDICAL REVIEW.—

"(1) IN GENERAL.—If a qualified external review entity determines under subsection (c) that a denial of a claim for benefits is eligible for independent medical review, the entity shall refer the denial involved to an independent medical reviewer for the conduct of an independent medical review under this subsection.

"(2) MEDICALLY REVIEWABLE DETERMINATIONS.—For purposes of this section, a denial of a claim for benefits is a medically reviewable determination if the benefit the item or service with respect to which the determination is made would be a covered benefit under the terms and conditions of the plan or coverage but for one (or more) of the following determinations:

"(A) DENIALS BASED ON MEDICAL NECESSITY AND APPROPRIATENESS.—The basis of the determination is that the item or service is not medically necessary and appropriate.

"(B) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—The basis of the determination is that the item or service is experimental or investigational.

"(C) DENIALS OTHERWISE BASED ON AN EVALUATION OF MEDICAL FACTS.—A determination that the item or service or condition is not covered but an evaluation of the medical facts by a health care professional in the specific case involved is necessary to determine whether the item or service or condition is required to be provided under the terms and conditions of the plan or coverage.

"(3) INDEPENDENT MEDICAL REVIEW DETERMINATION.—

"(A) IN GENERAL.—An independent medical reviewer under this section shall make a new independent determination with respect to—

"(i) whether the item or service or condition that is the subject of the denial is covered under the terms and conditions of the plan or coverage; and

"(ii) based upon an affirmative determination under clause (i), whether or not the denial of a claim for a benefit that is the subject of the review should be upheld or reversed.

"(B) STANDARD FOR DETERMINATION.—The independent medical reviewer's determination relating to the medical necessity and appropriateness, or the experimental or investigation nature, or the evaluation of the medical facts of the item, service, or condition shall be based on the medical condition of the participant or beneficiary (including the medical records of the participant or beneficiary) and the valid, relevant scientific evidence and clinical evidence. The independent medical reviewer may consider peer-reviewed medical literature or findings and peer-reviewed expert opinions and expert consensus. In determining the medical necessity and appropriateness of any item or service for which a claim for benefits is denied, the independent medical reviewer shall consider the effectiveness of the alternative items and services, if any, for which benefits were authorized by the plan or issuer involved for the participant or beneficiary.

"(C) NO COVERAGE FOR EXCLUDED BENEFITS.—Nothing in this subsection shall be construed to permit an independent medical reviewer to require that a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, provide coverage for items or services that are specifically excluded or expressly limited under the plan or coverage and that are not covered regardless of any determination relating to medical necessity and appropriateness, experimental or investiga-

tional nature of the treatment, or an evaluation of the medical facts in the case involved.

''(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the independent medical reviewer shall also consider appropriate and available evidence and information, including the following:

''(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence or guidelines used by the plan or issuer in reaching such determination.

''(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

''(iii) Additional evidence or information obtained by the reviewer or submitted by the plan, issuer, participant or beneficiary (or an authorized representative), or treating health care professional.

''(iv) The plan or coverage document.

''(E) INDEPENDENT DETERMINATION.—In making the determination, the independent medical reviewer shall—

''(i) consider the claim under review without deference to the determinations made by the plan or issuer under section 503A or the recommendation of the treating health care professional (if any); and

''(ii) consider, but not be bound by the definition used by the plan or issuer of 'medically necessary and appropriate', or 'experimental or investigational', or other equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or experimental or investigational nature of the treatment.

''(F) DETERMINATION OF INDEPENDENT MEDICAL REVIEWER.—An independent medical reviewer shall, in

accordance with the deadlines described in subsection (e), prepare a written determination to uphold or reverse the denial under review and, in the case of a reversal, the timeframe within which the plan or issuer shall authorize coverage to comply with the determination. Such written determination shall include the specific reasons of the reviewer for such determination, including a summary of the clinical or scientific-evidence based rationale used in making the determination. The reviewer may provide the plan or issuer and the treating health care professional with additional recommendations in connection with such a determination, but any such recommendations shall not be treated as part of the determination and shall not be admissible in any action under section 502.

"(e) TIMELINES AND NOTIFICATIONS.—

"(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

"(A) PRIOR AUTHORIZATION DETERMINATION.—

"(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 14 days after the receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services.

"(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), the independent medical reviewer (or reviewers) shall make an expedited determination on a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination, and the treating health care professional substantiates, with the request, that a determination under the timeline described in clause (i) would se-

riously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the receipt of information under subsection (c)(2).

"(iii) CONCURRENT DETERMINATION.—Notwithstanding clause (i), a review described in such subclause shall be completed not later than 24 hours after the receipt of information under subsection (c)(2) if the review involves a discontinuation of inpatient care.

"(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 30 days after the receipt of information under subsection (c)(2).

"(2) NOTIFICATION OF DETERMINATION.—The external review entity shall ensure that the plan or issuer, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing an entity or reviewer from providing an initial oral notice of the reviewer's determination.

"(3) FORM OF NOTICES.—Determinations and notices under this subsection shall be written in a manner calculated to be understood by an average participant.

"(4) TERMINATION OF EXTERNAL REVIEW PROCESS IF APPROVAL OF A CLAIM FOR BENEFITS DURING PROCESS.—

"(A) IN GENERAL.—If a plan or issuer—

"(i) reverses a determination on a denial of a claim for benefits that is the subject of an external review under this section and authorizes coverage for the claim or provides payment of the claim; and

"(ii) provides notice of such reversal to the participant or beneficiary (or authorized representative) and the treating health care professional (if any), and the external review entity responsible for such review,

the external review process shall be terminated with respect to such denial and any filing fee paid under subsection (b)(2)(A)(iv) shall be refunded.

"(B) TREATMENT OF TERMINATION.—An authorization of coverage under subparagraph (A) by the plan or issuer shall be treated as a written determination to reverse a denial under section (d)(3)(F) for purposes of liability under section 502(n)(1)(B).

"(f) COMPLIANCE.—

"(1) APPLICATION OF DETERMINATIONS.—

"(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent medical reviewer under this section shall be binding upon the plan or issuer involved.

"(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse the denial, the plan or issuer, upon the receipt of such determination, shall authorize coverage to comply with the medical reviewer's determination in accordance with the timeframe established by the medical reviewer under subsection (d)(3)(F).

"(2) FAILURE TO COMPLY.—

"(A) WITH TIMEFRAME FOR PROVIDING ITEMS AND SERVICES.—If a plan or issuer fails to comply with the timeframe established under paragraph (1)(B) with respect to a participant or beneficiary, where such failure to comply is caused by the plan or issuer, the participant or beneficiary may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from

any provider regardless of whether such provider is a participating provider under the plan or coverage.

"(B) REIMBURSEMENT.—

"(i) IN GENERAL.—Where a participant or beneficiary obtains items or services in accordance with subparagraph (A), the plan or issuer involved shall provide for reimbursement of the costs of such items or services. Such reimbursement shall be made to the treating health care professional or to the participant or beneficiary (in the case of a participant or beneficiary who pays for the costs of such items or services).

"(ii) AMOUNT.—The plan or issuer shall fully reimburse a professional, participant or beneficiary under clause (i) for the total costs of the items or services provided (regardless of any plan limitations that may apply to the coverage of such items or services) so long as—

"(I) the items or services would have been covered under the terms of the plan or coverage if provided by the plan or issuer; and

"(II) the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

"(C) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant or beneficiary in accordance with this paragraph, the professional, participant or beneficiary may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is unpaid and any necessary legal costs or expenses (including attorneys' fees) incurred in recovering such reimbursement.

"(g) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—

"(1) IN GENERAL.—In referring a denial to 1 or more individuals to conduct independent medical review under

subsection (c), the qualified external review entity shall ensure that—

"(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

"(B) with respect to each review at least 1 such reviewer meets the requirements described in paragraphs (4) and (5); and

"(C) compensation provided by the entity to the reviewer is consistent with paragraph (6).

"(2) LICENSURE AND EXPERTISE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer shall be a physician (who is an allopathic or osteopathic physician) or health care professional who—

"(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

"(ii) typically treats the diagnosis or condition or provides the type of treatment under review.

"(B) PHYSICIAN REVIEW.—In referring a denial for independent medical review under subsection (c), the qualified external review entity shall ensure that, in the case of the review of treatment that is recommended or provided by a physician, such referral may be made only to a physician for such independent medical review.

"(3) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

"(i) not be a related party (as defined in paragraph (7));

"(ii) not have a material familial, financial, or professional relationship with such a party; and

"(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

"(B) EXCEPTION.—Nothing in this subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of affiliation with the plan or issuer, from serving as an independent medical reviewer if—

"(I) a non-affiliated individual is not reasonably available;

"(II) the affiliated individual is not involved in the provision of items or services in the case under review;

"(III) the fact of such an affiliation is disclosed to the plan or issuer and the participant or beneficiary (or authorized representative) and neither party objects; and

"(IV) the affiliated individual is not an employee of the plan or issuer and does not provide services exclusively or primarily to or on behalf of the plan or issuer;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer if the affiliation is disclosed to the plan or issuer and the participant or beneficiary (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

"(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

"(A) IN GENERAL.—The requirement of this paragraph with respect to a reviewer in a case involving treatment, or the provision of items or services, by—

"(i) a physician, is that the reviewer be a practicing physician of the same or similar specialty as a physician who typically treats the diag-

nosis or condition or provides such treatment in the case under review; or

"(ii) a health care professional (other than a physician), is that the reviewer be a practicing physician or, if determined appropriate by the qualified external review entity, a health care professional (other than a physician), of the same or similar specialty as the health care professional who typically treats the diagnosis or condition or provides the treatment in the case under review.

"(B) PRACTICING DEFINED.—For purposes of this paragraph, the term 'practicing' means, with respect to an individual who is a physician or other health care professional that the individual provides health care services to individual patients on average at least 2 days per week.

"(5) PEDIATRIC EXPERTISE.—The independent medical reviewer shall have pediatric expertise under paragraph (2) where necessary to evaluate the relevant conditions for the participant or beneficiary involved.

"(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to an independent medical reviewer in connection with a review under this section shall—

"(A) not exceed a reasonable level; and

"(B) not be contingent on the determination rendered by the reviewer.

"(7) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a denial of a claim under a plan or coverage relating to a participant or beneficiary, any of the following:

"(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

"(B) The participant or beneficiary (or authorized representative).

"(C) The health care professional that provides the items of services involved in the denial.

"(D) The institution at which the items or services (or treatment) involved in the denial are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

"(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

"(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

"(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

"(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The Secretary shall implement procedures with respect to the selection of qualified external review entities by a plan or issuer to assure that the selection process among qualified external review entities will not create any incentives for external review entities to make a determination in a biased manner. No such selection process under the procedures implemented by the Secretary may give either the patient or the plan or issuer any ability to determine or influence the selection of a qualified external review entity to review the case of any participant or beneficiary.

"(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for the designation or selection of qualified external review entities in a manner determined by the State to assure an unbiased determination in conducting external review activities. In conducting reviews under this section, an entity designated or selected under this subparagraph shall comply with provisions of this section.

''(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

''(3) TERMS AND CONDITIONS OF CONTRACT.—The terms and conditions of a contract under paragraph (2) shall—

''(A) be consistent with the standards the Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external review activities; and

''(B) provide that the costs of the external review process shall be borne by the plan or issuer.

Subparagraph (B) shall not be construed as applying to the imposition of a filing fee under subsection (b)(2)(A)(iv) or costs incurred by the participant or beneficiary (or authorized representative) or treating health care professional (if any) in support of the review, including the provision of additional evidence or information.

''(4) QUALIFICATIONS.—

''(A) IN GENERAL.—In this section, the term 'qualified external review entity' means, in relation to a plan or issuer, an entity that is initially certified (and periodically recertified) under subparagraph (C) as meeting the following requirements:

''(i) The entity has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to carry out duties of a qualified external review entity under this section on a timely basis, including making determinations under subsection (b)(2)(A) and providing for independent medical reviews under subsection (d).

''(ii) The entity is not a plan or issuer or an affiliate or a subsidiary of a plan or issuer, and is

not an affiliate or subsidiary of a professional or trade association of plans or issuers or of health care providers.

''(iii) The entity has provided assurances that it will conduct external review activities consistent with the applicable requirements of this section and standards specified in subparagraph (C), including that it will not conduct any external review activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

''(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

''(v) The entity meets such other requirements as the Secretary provides by regulation.

''(B) INDEPENDENCE REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

''(I) is not a related party (as defined in subsection (g)(7));

''(II) does not have a material familial, financial, or professional relationship with such a party; and

''(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

''(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under this section if the compensation is provided consistent with clause (iii).

"(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by a plan or issuer to, or charged by, a qualified external review entity in connection with reviews under this section shall—

"(I) not exceed a reasonable level; and

"(II) not be contingent on the determination rendered by the entity or by any independent medical reviewer.

"(C) CERTIFICATION AND RECERTIFICATION PROCESS.—

"(i) IN GENERAL.—The initial certification and recertification of a qualified external review entity shall be made—

"(I) under a process that is recognized or approved by the Secretary; or

"(II) by a qualified private standard-setting organization that is approved by the Secretary under clause (iii).

The Secretary shall promulgate regulations setting forth the process described in subclause (I).

"(ii) PROCESS.—The Secretary shall not recognize or approve a process under clause (i)(I) unless the process applies standards (as promulgated in regulations) that ensure that a qualified external review entity—

"(I) will carry out (and has carried out, in the case of recertification) the responsibilities of such an entity in accordance with this section, including meeting applicable deadlines;

"(II) will meet (and has met, in the case of recertification) appropriate indicators of fiscal integrity;

"(III) will maintain (and has maintained, in the case of recertification) appropriate confidentiality with respect to individually identifi-

able health information obtained in the course of conducting external review activities; and

"(IV) in the case recertification, shall review the matters described in clause (iv).

"(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the Secretary may approve a qualified private standard-setting organization if the Secretary finds that the organization only certifies (or recertifies) external review entities that meet at least the standards required for the certification (or recertification) of external review entities under clause (ii).

"(iv) CONSIDERATIONS IN RECERTIFICATIONS.—In conducting recertifications of a qualified external review entity under this paragraph, the Secretary or organization conducting the recertification shall review compliance of the entity with the requirements for conducting external review activities under this section, including the following:

"(I) Provision of information under subparagraph (D).

"(II) Adherence to applicable deadlines (both by the entity and by independent medical reviewers it refers cases to).

"(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers cases to).

"(IV) Compliance with applicable independence requirements.

"(V) Quality and consistency of medical review determinations with valid, relevant scientific and clinical evidence, as provided under clause (vii).

"(v) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification pro-

vided under this paragraph shall extend for a period not to exceed 3 years.

''(vi) REVOCATION.—A certification or recertification under this paragraph may be revoked by the Secretary or by the organization providing such certification upon a showing of cause.

''(vii) ASSURANCE OF QUALITY AND CONSISTENCY WITH VALID, RELEVANT SCIENTIFIC AND CLINICAL EVIDENCE OF EXTERNAL REVIEW DETERMINATIONS.—The standards applied under this subparagraph shall include procedures, promulgated by the Secretary in consultation with the Secretary of Health and Human Services, to assure that each qualified external review entity is accountable for the quality and consistency of the external review determinations made by its independent medical reviewers with valid, relevant scientific and clinical evidence.

''(D) PROVISION OF INFORMATION.—

''(i) IN GENERAL.—A qualified external review entity shall provide to the Secretary, in such manner and at such times as the Secretary may require, such information (relating to the denials which have been referred to the entity for the conduct of external review under this section) as the Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include individually identifiable medical information.

''(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

"(I) The number and types of denials for which a request for review has been received by the entity.

"(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

"(III) The length of time in making determinations with respect to such denials.

"(IV) Updated information on the information required to be submitted as a condition of certification with respect to the entity's performance of external review activities.

"(iii) INFORMATION TO BE PROVIDED TO CERTIFYING ORGANIZATION.—

"(I) IN GENERAL.—In the case of a qualified external review entity which is certified (or recertified) under this subsection by a qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the Secretary under clause (i).

"(II) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as preventing such an organization from requiring additional information as a condition of certification or recertification of an entity.

"(iv) USE OF INFORMATION.—

"(I) IN GENERAL.—Information provided under this subparagraph may be used by the Secretary and qualified private standard-setting organizations to conduct oversight of qualified external review entities, including recertification of such entities, and shall be made available to the public in an appropriate manner.

"(II) REPORT TO CONGRESS.—Not later than 2 years after the date on which the Patients' Bill of Rights Act of 2001 takes effect under section 501 of such Act, and every 2 years thereafter, the Secretary, in consultation with the Secretary of Health and Human Services, shall prepare and submit to the appropriate committees of Congress, a report that contains—

"(aa) a summary of the information provided to the Secretary under clause (ii);

"(bb) a description of the effect that the appeals process established under this section and section 503A had on the access of individuals to health insurance and health care;

"(cc) a description of the effect on health care costs associated with the implementation of the appeals process described in item (bb); and

"(dd) a description of the quality and consistency of determinations by qualified external review entities.

"(III) RECOMMENDATIONS.—The Secretary may from time to time submit recommendations to Congress with respect to proposed modifications to the appeals process based on the reports submitted under subclause (II).

"(E) LIMITATION ON LIABILITY.—No qualified external review entity having a contract with a plan or issuer, and no person who is employed by any such entity or who furnishes professional services to such entity (including as an independent medical reviewer), shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to be civilly liable under any law of the United

States or of any State (or political subdivision thereof) if there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

''(i) DEFINITIONS AND RELATED RULES.—For purposes of this section—

''(1) AUTHORIZED REPRESENTATIVE.—The term 'authorized representative' means, with respect to a participant or beneficiary—

''(A) a person to whom a participant or beneficiary has given express written consent to represent the participant or beneficiary in any proceeding under this section;

''(B) a person authorized by law to provide substituted consent for the participant or beneficiary; or

''(C) a family member of the participant or beneficiary (or the estate of the participant or beneficiary) or the participant's or beneficiary's treating health care professional when the participant or beneficiary is unable to provide consent.

''(2) CLAIM FOR BENEFITS.—The term 'claim for benefits' means any request by a participant or beneficiary (or authorized representative) for benefits, for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage offered by a health insurance issuer in connection with a group health plan.

''(3) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a).

''(4) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1).

''(5) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

''(6) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a deter-

mination by the group health plan or health insurance issuer offering health insurance coverage in connection with a group health plan prior to the provision of the items and services as a condition of coverage of the items and services under the terms and conditions of the plan or coverage.

''(7) TREATING HEALTH CARE PROFESSIONAL.—The term 'treating health care professional' with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

''(8) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means procedures used in the determination of coverage for a participant or beneficiary, such as procedures to evaluate the medical necessity, appropriateness, efficacy, quality, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

''(9) TREATMENT OF EXCEPTED BENEFITS.—The requirements of this section and section 503A shall not apply to excepted benefits (as defined in section 733(c)), other than benefits described in section 733(c)(2)(A), in the same manner as the provisions of part 7 do not apply to such benefits under subsections (b) and (c) of section 732.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 503 the following:

''Sec. 503A. Claims and internal appeals procedures for group health plans.
''Sec. 503B. Independent external appeals procedures for group health plans.''.

SEC. 132. ENFORCEMENT.

(a) CIVIL PENALTY AUTHORITY.—Section 502(c) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)) is amended—

(1) by redesignating paragraph (7) as paragraph (8); and

(2) by inserting after paragraph (6) the following new paragraph:in subsection (a)(1)(A), by inserting ''or (n)'' after ''subsection (c)''; and

''(7)(A) In the case of—

''(i) a failure described in section 503B(f)(2)(A) (relating to failure to comply with timeframe for providing items and services), or

''(ii) a failure of a group health plan or health insurance issuer to take such actions as are necessary to refer a denial of a claim for benefit to independent medical review in accordance with section 503B(c)(1) or to provide information required in connection with such a referral under section 503B(c)(2),

the Secretary may assess a civil penalty in an amount determined under subparagraph (B) against any person who, acting in the capacity of authorizing the benefit involved, causes such failure.

''(B)(i) Subject to clause (iii), such civil penalty shall not exceed the amount specified in clause (ii) for each day from the date of commencement of such failure until the date the failure is corrected.

''(ii) The amount specified in this clause for any day described in clause (i) shall be—

''(I) $2,000 a day for the 1st through the 7th days,

''(II) $5,000 a day for the 8th through the 14th days, and

''(III) $10,000 a day for each day after the 14th day.

''(iii) The total amount of the penalty under clause (i) may not exceed $500,000.

''(C) Civil monetary penalties under the preceding provisions of this paragraph may be imposed against authorized offi-

cials for failure to provide referral to a qualified external review entity or access to health information, as required under section 503B(c)(1) and (2).

"(D)(i) In addition to any penalty imposed under subparagraph (A), the Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more group health plans, or health insurance issuers offering health insurance coverage, for any pattern or practice of repeated violations of the requirements of this section with respect to such plan or coverage (including any failure described in subparagraph (A)(i) or the refusal to authorize a benefit determined by an external appeal entity to be covered).

"(ii) Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed for such pattern or practice the lesser of—

"(I) 25 percent of the aggregate value of benefits shown by the Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice; or

"(II) $500,000.

"(iii) Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in clause (i) with respect to a plan or coverage, upon the petition of the Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

"(E) In any action under this paragraph to collect a civil penalty under subparagraph (A) or (D), the court shall cause to be served on the defendant an order requiring the defendant—

"(i) to cease and desist from the alleged failure to act; and

''(ii) to pay to the Secretary a reasonable attorney's fee and other reasonable costs relating to the prosecution of the action on the charges on which the Secretary prevails.

''(F) The preceding provisions of this paragraph shall not apply with respect to employee benefit plans that are not group health plans. Such provisions also shall not apply to excepted benefits (as defined in section 733(c)), other than benefits described in section 733(c)(2)(A), in the same manner as the provisions of part 7 do not apply to such benefits under subsections (b) and (c) of section 732.

''(G) The remedies provided under this paragraph are in addition to any other available remedies.''.

(b) CONFORMING AMENDMENT.—Section 502(a)(6) of such Act (29 U.S.C. 1132(a)(6)) is amended by striking ''or (6)'' and inserting ''(6), or (7)''.

Subtitle D—Remedies

SEC. 141. AVAILABILITY OF COURT REMEDIES.

(a) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following:

''(n) CAUSE OF ACTION RELATING TO DENIAL OF A CLAIM FOR HEALTH BENEFITS.—

''(1) IN GENERAL.—

''(A) FAILURE TO COMPLY WITH EXTERNAL MEDICAL REVIEW.—With respect to an action commenced by a participant or beneficiary (or the estate of the participant or beneficiary) in connection with a claim for benefits under a group health plan, if—

''(i) a designated decisionmaker described in paragraph (2) fails to exercise ordinary care in failing to authorize coverage in compliance with the written determination of an independent medical reviewer under section 503B(d)(3)(F) that reverses a denial of the claim for benefits; and

"(ii) the failure described in clause (i) is the proximate cause of substantial harm (as defined in paragraph (14)(G)) to the participant or beneficiary;

such designated decisionmaker shall be liable to the participant or beneficiary (or the estate) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

"(B) WRONGFUL DETERMINATION RESULTING IN DELAY IN PROVIDING OR FAILURE TO RECEIVE BENEFITS.—With respect to an action commenced by a participant or beneficiary (or the estate of the participant or beneficiary) in connection with a claim for benefits under a group health plan, if—

"(i) a designated decisionmaker described in paragraph (2)—

"(I) fails to exercise ordinary care in making a determination denying the claim for benefits under section 503A(a) (relating to an initial claim for benefits); or

"(II) fails to exercise ordinary care in making a determination denying the claim for benefits under section 503A(b) (relating to an internal appeal);

"(ii) the denial described in clause (i)—

"(I) is reversed by an independent medical reviewer under section 503B(d) or 503B(e)(4)(B), or

"(II) was determined by a qualified external review entity under section 503B(c)(3) not to be eligible for referral for independent medical review under such section; and

"(iii) the delay in receiving, or failure to receive, benefits attributable to the failure described in clause (i) is the proximate cause of substantial

harm to, or the wrongful death of, the participant or beneficiary;

such designated decisionmaker shall be liable to the participant or beneficiary (or the estate) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

"(C) LIMITATION ON LIABILITY BASED ON APPOINTMENT OF DESIGNATED DECISIONMAKER.—If a plan sponsor or named fiduciary appoints a designated decisionmaker in accordance with paragraph (2), the plan sponsor or named fiduciary, or any other person or group health plan (or their employees) associated with the plan sponsor or named fiduciary, shall not be liable under this paragraph. The appointment of a designated decisionmaker in accordance with paragraph (2) shall not affect the liability of the appointing plan sponsor or named fiduciary for the failure of the plan sponsor or named fiduciary to comply with any other requirement of this title.

"(2) DESIGNATED DECISIONMAKER.—

"(A) APPOINTMENT.—

"(i) IN GENERAL.—The plan sponsor or named fiduciary of a group health plan shall, in accordance with this paragraph, designate one or more persons to serve as a designated decisionmaker with respect to causes of action described in subparagraphs (A) and (B) of paragraph (1), except that—

"(I) with respect to health insurance coverage offered in connection with a group health plan, the health insurance issuer shall be the designated decisionmaker unless the plan sponsor and the issuer specifically agree in writing (on a form to be prescribed by the Secretary) to substitute another person as the designated decisionmaker; or

"(II) with respect to the designation of a person other than a plan sponsor or health insurance issuer, such person shall satisfy the requirements of subparagraph (D).

"(ii) PLAN DOCUMENTS.—The designated decisionmaker shall be specifically designated as such in the written instruments of the plan (under section 402(a)) and be identified as required under section 121(b)(14) of the Patients' Bill of Rights Act of 2001.

"(B) AUTHORITY.—A designated decisionmaker appointed under subparagraph (A) shall have the exclusive authority under the group health plan—

"(i) to make determinations with respect to a claim for benefits under section 503A(a) (relating to an initial claim for benefits);

"(ii) to make final determinations under section 503A(b) (relating to an internal appeal); or

"(iii) to approve coverage pursuant to the written determination of independent medical reviewers under section 503B.

"(C) ALLOCATION OF RESPONSIBILITY.—Responsibility may be allocated among different designated decisionmakers with respect to—

"(i) for purposes of paragraph (1)(A), the approval of coverage under section 503B;

"(ii) for purposes of paragraph (1)(B), making determinations on a claim for benefits under section 503A(a) (relating to an initial claim for benefits); and

"(iii) for purposes of paragraph (1)(B), making final determinations on claims for benefits under section 503A(b) (relating to internal appeals).

Where such an allocation is made, liability under a cause of action under paragraph (1) shall be assessed against the appropriate designated decisionmaker.

"(D) QUALIFICATIONS.—

"(i) CERTIFICATION OF ABILITY.—To be appointed as a designated decisionmaker under this paragraph, a person shall provide to the plan sponsor or named fiduciary a certification of such person's ability to meet the requirement of clause (ii) and the requirements of clause (iii) (relating to financial obligation for liability under this subsection). Such certification shall be provided upon appointment and not less frequently than annually thereafter, or if the designation is pursuant to a multi-year contract, in conjunction with the renewal of the contract, but in no case less than once every 3 years.

"(ii) TREATING PHYSICIAN NOT ELIGIBLE.—The treating physician of a participant or beneficiary is not qualified to be appointed as a designated decisionmaker under this paragraph with respect to claims for benefits of such participant or beneficiary relating to the services of that physician.

"(iii) OTHER REQUIREMENTS RELATING TO FINANCIAL OBLIGATIONS.—For purposes of clause (i), requirements relating to financial obligation for liability shall include evidence of—

"(I) coverage of the person under insurance policies or other arrangements, secured and maintained by the person, to insure the person against losses arising from professional liability claims, including those arising from being designated as a designated decisionmaker under this paragraph; or

"(II) minimum capital and surplus levels that are maintained by the person to cover any losses as a result of liability arising from being designated as a designated decisionmaker under this paragraph.

The appropriate amounts of liability insurance and minimum capital and surplus levels for purposes of subclauses (I) and (II) shall be determined by an actuary using sound actuarial principles and accounting practices pursuant to established guidelines of the American Academy of Actuaries and shall be maintained throughout the course of the contract in which such person is designated as a designated decisionmaker.

''(E) FLEXIBILITY IN ADMINISTRATION.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may provide—

''(i) that any person or group of persons may serve in more than one capacity with respect to the plan or coverage (including service as a designated decisionmaker, administrator, and named fiduciary); or

''(ii) that a designated decisionmaker may employ one or more persons to provide advice with respect to any responsibility of such decisionmaker under the plan or coverage.

''(F) FAILURE TO APPOINT.—With respect to any cause of action under paragraph (1) relating to a denial of a claim for benefits where a designated decisionmaker has not been appointed in accordance with this paragraph, the plan sponsor or named fiduciary responsible for determinations under section 503 shall be deemed to be the designated decisionmaker.

''(3) REQUIREMENT OF EXHAUSTION OF INDEPENDENT MEDICAL REVIEW.—

''(A) IN GENERAL.—Paragraph (1) shall apply only if—

''(i) a final determination denying a claim for benefits under section 503A(b) has been referred for independent medical review under section 503B(d) and a written determination by an inde-

pendent medical reviewer to reverse such final determination has been issued with respect to such review, or

"(ii) the qualified external review entity has determined under section 503B(c)(3) that a referral to an independent medical reviewer is not required.

"(B) INJUNCTIVE RELIEF FOR IRREPARABLE HARM.—A participant or beneficiary may seek relief under subsection 502(a)(1)(B) prior to the exhaustion of administrative remedies under section 503A(b) or 503B (as required under subparagraph (A)) if it is demonstrated to the court, by a preponderance of the evidence, that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503A or 503B in such case, or that are made in such case while an action under this subparagraph is pending, shall be given due consideration by the court in any action under this subsection in such case. Notwithstanding the awarding of relief under subsection 502(a)(1)(B) pursuant to this subparagraph, no relief shall be available under—

"(i) paragraph (1), with respect to a participant or beneficiary, unless the requirements of subparagraph (A) are met; or

"(ii) subsection (q) unless the requirements of such subsection are met.

"(4) LIMITATIONS ON RECOVERY OF DAMAGES.—

"(A) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—The aggregate amount of liability for noneconomic loss in an action under paragraph (1) may not exceed $500,000.

"(B) SEVERAL LIABILITY.—In the case of any action commenced pursuant to paragraph (1), the designated decisionmaker shall be liable only for the amount of damages attributable to such designated de-

cisionmaker in direct proportion to such decisionmaker's share of fault or responsibility for the injury suffered by the participant or beneficiary. In all such cases, the liability of a designated decisionmaker for damages shall be several and not joint.

"(C) PROHIBITION OF AWARD OF PUNITIVE DAMAGES.—Notwithstanding any other provision of law, in the case of any action commenced pursuant to paragraph (1), the court may not award any punitive, exemplary, or similar damages against a defendant.

"(5) AFFIRMATIVE DEFENSES.—In the case of any cause of action under paragraph (1), it shall be an affirmative defense that—

"(A) the designated decisionmaker of a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, involved did not receive from the participant or beneficiary (or authorized representative) or the treating health care professional (if any), the information requested by the plan or issuer regarding the medical condition of the participant or beneficiary that was necessary to make a determination on a claim for benefits under section 503A(a) or a final determination on a claim for benefits under section 503A(b);

"(B) the participant or beneficiary (or authorized representative) or treating health care professional—

"(i) was in possession of facts that were sufficient to enable the participant or beneficiary (or authorized representative) to know that an expedited review under section 503A or 503B would have prevented the harm that is the subject of the action; and

"(ii) failed to notify the plan or issuer of the need for such an expedited review; or

"(C) the qualified external review entity or an independent medical reviewer failed to meet the

timelines applicable under section 503B, or a period of time elapsing after coverage has been authorized.

Nothing in this paragraph shall be construed to limit the application of any other affirmative defense that may be applicable to the cause of action involved.

''(6) WAIVER OF INTERNAL REVIEW.—In the case of any cause of action under paragraph (1), the waiver or nonwaiver of internal review under section 503A(b)(1)(D) by the group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall not be used in determining liability.

''(7) LIMITATIONS ON ACTIONS.—Paragraph (1) shall not apply in connection with any action that is commenced more than 5 years after the date on which the failure described in such paragraph occurred or, if earlier, not later than 2 years after the first date the participant or beneficiary became aware of the substantial harm referred to in such paragraph.

''(8) EXCLUSION OF DIRECTED RECORDKEEPERS.—

''(A) IN GENERAL.—Paragraph (1) shall not apply with respect to a directed record keeper in connection with a group health plan.

''(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed record keeper' means, in connection with a group health plan, a person engaged in directed record keeping activities pursuant to the instructions of the plan, the employer, or another plan sponsor, including the distribution of enrollment information and distribution of disclosure materials under this Act or the Public Health Service Act and whose duties do not include making determinations on claims for benefits.

''(9) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A

claim that is based on or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503B(i)(2) and notwithstanding the definition contained in paragraph (14)(B)) shall not be deemed to be the delivery of medical care under any State law for purposes of this section. Any such claim shall be maintained exclusively under section 502. Nothing in this paragraph shall be construed as affecting any action under State law that is permitted under section 514(c).

"(10) COORDINATION WITH FIDUCIARY REQUIREMENTS.—A fiduciary shall not be treated as failing to meet any requirement of part 4 solely by reason of any action taken by a fiduciary which consists of full compliance with the reversal under section 503B (relating to independent external appeals procedures for group health plans) of a denial of claim for benefits (within the meaning of section 503B(i)(2)).

"(11) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing a cause of action under paragraph (1) for the failure of a group health plan or health insurance issuer to provide an item or service that is specifically excluded under the plan or coverage.

"(12) LIMITATION ON CLASS ACTION LITIGATION.—A claim or cause of action under this subsection may not be maintained as a class action, as a derivative action, or as an action on behalf of any group of 2 or more claimants.

"(13) PREVENTION OF DUPLICATION OF ACTION WITH ACTION UNDER STATE LAW.—No action may be brought under this subsection based upon facts and circumstances if a cause of action under State law (that is permitted under section 514 only because of the application of subsection (c) of such section) is brought based upon the same facts and circumstances.

"(14) DEFINITIONS AND RELATED RULES.—For purposes of this subsection:

"(A) AUTHORIZED REPRESENTATIVE.—The term 'authorized representative' has the meaning given such term in section 503B(i).

"(B) CLAIM FOR BENEFITS.—Except as provided for in paragraph (8), the term 'claim for benefits' shall have the meaning given such term in section 503B(i), except that such term shall only include claims for prior authorization determinations (as such term is defined in section 503B(i)).

"(C) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a).

"(D) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1).

"(E) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

"(F) ORDINARY CARE.—The term 'ordinary care' means the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent individual acting in a like capacity and familiar with such matters would use in making a determination on a claim for benefits of a similar character.

"(G) SUBSTANTIAL HARM.—The term 'substantial harm' means the loss of life, loss or significant impairment of limb or bodily function, significant mental illness or disease, significant disfigurement, or severe and chronic physical pain.

"(H) TREATMENT OF EXCEPTED BENEFITS.—The provisions of this subsection shall not apply to excepted benefits (as defined in section 733(c)), other than benefits described in section 733(c)(2)(A), in the same manner as the provisions of part 7 do not apply to such benefits under subsections (b) and (c) of section 732.".

(b) CONFORMING AMENDMENT.—Section 502(a)(1)(A) of the Employee Retirement Income Security Act of 1974 (29

U.S.C. 1132(a)(1)(A)) is amended by inserting ''or (n)'' after ''subsection (c)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to acts and omissions occurring on or after the effective date contained in section 501 of this Act.

SEC. 142. TREATMENT OF STATE CAUSES OF ACTION WITH RESPECT TO CERTAIN CLAIMS DENIALS BY GROUP HEALTH PLANS.

Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended—

(1) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (b) the following new subsection:

''(c) TREATMENT OF STATE CAUSES OF ACTION WITH RESPECT TO CERTAIN CLAIMS DENIALS BY GROUP HEALTH PLANS.—

''(1) IN GENERAL.—Notwithstanding the preceding provisions of this section, a cause of action by a participant or beneficiary under a group health plan against the applicable designated decisionmaker (within the meaning of section 502(o)) under State law is not superseded by the provisions of this title if—

''(A) the action is one for damages from personal injury or for wrongful death proximately caused by a denial of a claim for benefits, and

''(B) the conditions described in paragraph (2) are met with respect to such denial.

''(2) FAILURE TO AUTHORIZE COVERAGE ORDERED BY INDEPENDENT MEDICAL REVIEWER.—The conditions in this paragraph with respect to a denial of a claim for benefits are met if—

''(A) the denial is reversed by a written determination by an independent medical reviewer under section 503B(d)(3)(F); and

''(B) there has been a failure to authorize coverage in compliance with such written determination.

"(3) PREVENTION OF DUPLICATION OF ACTION WITH ACTION UNDER FEDERAL LAW.—Paragraph (1) shall not apply, in relation to a cause of action under State law based upon facts and circumstances, if a cause of action is brought under section 502(n) based upon the same facts and circumstances.

"(4) DEFINITIONS AND RELATED RULES.—For purposes of this subsection—

"(A) CLAIM FOR BENEFITS.—The term 'claim for benefits' has the meaning provided such term under section 503B(i)(2).

"(B) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning provided such term under section 733(a)(1), except that such term includes a plan, fund, or program treated as a group health plan under section 732(d).

"(C) TREATMENT OF EXCEPTED BENEFITS.—The provisions of this subsection shall not apply to excepted benefits (as defined in section 733(c)), other than benefits described in section 733(c)(2)(A), in the same manner as the provisions of part 7 do not apply to such benefits under subsections (b) and (c) of section 732.".

SEC. 143. LIMITATION ON CERTAIN CLASS ACTION LITIGATION.

(a) ERISA.—

(1) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by section 141, is further amended by adding at the end the following:

"(o) LIMITATION ON CLASS ACTION LITIGATION.—Any claim or cause of action that is maintained under this section (other than under subsection (n)) or under section 1962 or 1964(c) of title 18, United States Code, in connection with a group health plan, or health insurance coverage issued in connection with a group health plan, as a class action, derivative action, or as an action on behalf of any group of 2 or more claimants, may be maintained only if the class, the derivative

claimant, or the group of claimants is limited to the participants or beneficiaries of a group health plan established by only 1 plan sponsor. No action maintained by such class, such derivative claimant, or such group of claimants may be joined in the same proceeding with any action maintained by another class, derivative claimant, or group of claimants or consolidated for any purpose with any other proceeding. In this paragraph, the terms 'group health plan' and 'health insurance coverage' have the meanings given such terms in section 733.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to actions commenced on or after June 26, 2001. Notwithstanding the preceding sentence, with respect to class actions, the amendment made by paragraph (1) shall apply with respect to civil actions which are pending on such date in which a class action has not been certified as of such date.

(b) RICO.—

(1) IN GENERAL.—Section 1964(c) of title 18, United States Code, is amended—

(A) by inserting ''(1)'' after the subsection designation; and

(B) by adding at the end the following:

''(2) No action may be brought under this subsection, or alleging any violation of section 1962, where the action seeks relief concerning the manner in which any person has marketed, provided information concerning, established, administered, or otherwise operated a group health plan, or health insurance coverage in connection with a group health plan. Any such action shall only be brought under the Employee Retirement Income Security Act of 1974. In this paragraph, the terms 'group health plan' and 'health insurance issuer' shall have the meanings given such terms in section 733 of the Employee Retirement Income Security Act of 1974.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to actions commenced on or after June 26, 2001.

Subtitle E—State Flexibility

SEC. 151. STATE FLEXIBILITY IN APPLYING REQUIREMENTS TO HEALTH INSURANCE ISSUERS AND NON-FEDERAL GOVERNMENTAL GROUP HEALTH PLANS.

(a) NONAPPLICATION OF CERTAIN FEDERAL REQUIREMENTS IN CASE OF QUALIFIED STATE REGULATION.—

(1) IN GENERAL.—

(A) QUALIFIED STATE PATIENT PROTECTIONS.—A patient protection requirement shall not apply with respect to health insurance coverage (and to a group health plan insofar as it provides benefits in the form of health insurance coverage) if there is a State law (as defined in subsection (c)) that regulates such coverage and that is substantially equivalent (as provided under paragraph (2) or (4)) to such requirement.

(B) INTERNAL AND EXTERNAL APPEALS.—The requirements of section 503A or 503B of the Employee Retirement Income Security Act of 1974 shall not apply with respect to individual health insurance coverage or to a non-Federal governmental group health plan if there is a State law that regulates such coverage or plan and that is substantially equivalent (as provided under paragraph (2) or (4)) to the section.

(C) PATIENT PROTECTION REQUIREMENT DEFINED.—For purposes of this section, the term ''patient protection requirement'' means any one or more requirements under the following:

(i) Section 101 (relating to access to emergency care).

(ii) Section 102 (relating to consumer choice option) with respect to non-Federal governmental plans only.

(iii) Section 103 (relating to patient access to obstetric and gynecological care).

(iv) Section 104 (relating to access to pediatric care).

(v) Section 105 (relating to timely access to specialists).

(vi) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

(vii) Section 108 (relating to access to needed prescription drugs).

(viii) Section 109 (relating to coverage for individuals participating in approved clinical trials).

(ix) A prohibition under—

(I) section 107 (relating to prohibition of interference with certain medical communications); and

(II) section 110 (relating to prohibition of discrimination against providers based on licensure).

(x) An informational requirement under section 121.

(2) STATE CERTIFICATION OF SUBSTANTIAL EQUIVALENCE.—

(A) IN GENERAL.—For purposes of paragraph (1), a State law that imposes requirements that relate to a section in Federal law referred to in such paragraph is deemed to be substantially equivalent to that section if the chief executive officer of the State, not later than the deadline specified in subparagraph (D), submits to the Secretary of Health and Human Services a certification described in subparagraph (B). Such certification shall be effective under paragraph (1) until otherwise provided under paragraph (3)(C) or (3)(D).

(B) DESCRIPTION OF CERTIFICATION.—A certification described in this subparagraph is, with respect to a State law in relation to a section of Federal law referred to in paragraph (1), a certification that there is a reasonable basis to find that the State law imposes requirements that, taken as a whole and considering the need for flexibility in the application of such section

in relation to applicable State law, provide protections that are substantially equivalent to or greater than the protections to participants and beneficiaries provided under such section.

(C) PROCEDURES.—The Secretary of Health and Human Services shall by regulation establish procedures to carry out this subsection.

(D) DEADLINE.—The deadline specified in this subparagraph is 90 days after the date regulations described in subparagraph (C) are first promulgated.

(3) OPPORTUNITY FOR SECRETARIAL REVIEW AND DETERMINATION.—

(A) NOTICE OF RECEIPT OF CERTIFICATION.—The Secretary of Health and Human Services shall provide for public notice upon receipt of a certification submitted under paragraph (2). Such Secretary may review such a certification to determine preliminarily whether there is a reasonable basis for the certification.

(B) NOTICE OF PRELIMINARY DISAPPROVAL.—A certification under paragraph (2) shall be effective unless such Secretary determines, within 90 days of the date of its submittal, that there is not a reasonable basis for the certification. Such Secretary shall provide notice to the State and the public of such determination. Such notice shall include an explanation of the basis for the determination and shall identify specific deficiencies in the State law. The provision of such notice shall not suspend the effectiveness of the State certification.

(C) FINAL DETERMINATION.—If such Secretary has made a determination described in subparagraph (B), such Secretary shall make a final determination regarding whether there is a reasonable basis for the certification. Such Secretary shall provide notice of such final determination in the same manner as for determinations under subparagraph (B). If such Secretary decides that there is not a reasonable basis for

the certification, such Secretary shall specify a time period (of not less than one year) by the end of which the certification will no longer be effective. Such determination shall take effect (and the effectiveness of the certification suspended) at the end of the period for filing judicial review of such determination under subparagraph (D) unless the State files for judicial review. If the State files for judicial review the certification shall remain in effect during the period of judicial review and until such time as ordered by the court under subparagraph (D).

(D) JUDICIAL REVIEW.—A final determination of the Secretary under subparagraph (C) is subject to judicial review under chapter 5 of title 5, United States Code, in the Circuit Court of Appeals for the State certification of which is challenged. To find for such Secretary, the court must find that there is not a reasonable basis for the certification. If the court upholds the final determination of such Secretary, the certification shall remain in effect until such date as the court may specify in order to provide for an orderly transition.

(4) STATE CERTIFICATIONS AFTER FEDERAL PROVISIONS HAVE TAKEN EFFECT.—After a section of Federal law referred to in paragraph (1) has taken effect, a State may nonetheless submit a certification described in paragraph (2)(B). Such a certification shall only become effective if—

(A) there is no challenge of the certification by the Secretary of Health and Human Services within 90 days after the date of its submittal;

(B) such Secretary concurs in the certification; or

(C) such Secretary challenges the certification but such challenge is not upheld in court;

and not until 1 year after the expiration of such 90-day period, the date of the Secretary's concurrence, or the date a court does not uphold the Secretary's challenge, as the case may be.

(b) RELATIONSHIP OF QUALIFIED STATE PATIENT PROTECTIONS TO PLANS UNDER ERISA.—

(1) IN GENERAL.—Nothing in this section shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) with respect to group health plans. In any case in which health insurance coverage is provided by a health insurance issuer in connection with a group health plan to which title I of such Act applies and there is a State law described in subsection (a)(1)(A) that regulates such coverage and that is substantially equivalent (as provided under paragraph (2) or (4) of subsection (a)) to requirements of a section of Federal law referred to in subsection (a)(1)(A), to the extent that such State law, as applicable to such plan, is superseded by such title, the provisions of such State law shall be deemed (including for purposes of applying administration and enforcement of part 5 of subtitle B of title I of such Act) to be substituted for (and incorporated as) the corresponding section of Federal law referred to in subsection (a)(1)(A) insofar as the plan provides benefits by means of such coverage.

(2) PREVENTING APPLICATION OF STATE LAW IN CASES WHERE FEDERAL LAW IS APPLIED.—In any case in which, after applying the provisions of this subsection with respect to a section of Federal law described referred to in subsection (a)(1)(A), the requirements of such section remain applicable with respect to health insurance coverage (and to a group health plan insofar as it provides benefits in the form of health insurance coverage) in a State, any State law that imposes requirements within the scope of the subject matter and protections provided by such section, taken as a whole, is preempted and does not apply.

(c) DEFINITIONS.—For purposes of this section, the terms ''State'' and ''State law'' shall have the meanings given such terms in section 2723(d) of the Public Health Service Act (42 U.S.C. 300gg–23(d)).

Subtitle F—Miscellaneous Provisions

SEC. 161. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 of the Public Health Service Act shall apply for purposes of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term ''Secretary'' means the Secretary of Health and Human Services, in consultation with the Secretary of Labor.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) ENROLLEE.—The term ''enrollee'' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

(2) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

(3) HEALTH CARE PROVIDER.—The term ''health care provider'' includes an allopathic or osteopathic physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

(4) NETWORK.—The term ''network'' means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

(5) NONPARTICIPATING.—The term ''nonparticipating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health

insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(6) PARTICIPATING.—The term ''participating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

(7) PRIOR AUTHORIZATION.—The term ''prior authorization'' means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

(8) TERMS AND CONDITIONS.—The term ''terms and conditions'' includes, with respect to a group health plan or health insurance coverage, requirements imposed under this title (and sections 503A and 503B of the Employee Retirement Income Security Act of 1974) with respect to the plan or coverage.

SEC. 162. EXCLUSIONS.

(a) NO BENEFIT REQUIREMENTS.—Nothing in this title (or the amendments made by this title) shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to provide specific benefits under the terms of such plan or coverage, other than those provided under the terms of such plan or coverage.

(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

(1) IN GENERAL.—The provisions of subtitle A shall not apply to a group health plan or health insurance coverage if the only coverage offered under such plan or coverage is fee-for-service coverage (as defined in paragraph (2)).

(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of this subsection, the term ''fee-for-service coverage'' means coverage under a group health plan or health insurance coverage that—

(A) reimburses hospitals, health professionals, and other providers on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary reimbursement for such a provider based on an agreement to contract terms or the utilization of health care items or services relating to such provider;

(C) allows access to any provider that is lawfully authorized to provide the covered services and agree to accept the terms of payment established under the plan or by the issuer; and

(D) for which the plan or issuer does not require prior authorization before providing for any health care services.

Notwithstanding subparagraph (D), coverage that would satisfy the coverage requirements established for an indemnity benefit plan or a service benefit plan under the Federal employees health benefits program under chapter 89 of title 5, United States Code, and any related regulations and rules promulgated by the Office of Personnel Management, shall be considered to meet the definition of fee-for-service coverage under this paragraph.

(c) TREATMENT OF EXCEPTED BENEFITS.—The requirements of this title shall not apply to excepted benefits (as defined in section 733(c) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1191b(c)), other than benefits described in section 733(c)(2)(A) of such Act, in the same manner as the provisions of part 7 of subtitle B of title I of such Act do not apply to such benefits under subsections (b) and (c) of section 732 of such Act (29 U.S.C. 1191a).

(d) RULE WITH RESPECT TO CERTAIN PLANS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, health insurance issuers may offer, and eligible individuals may purchase, high deductible health plans described in section 220(c)(2)(A) of the Internal Revenue Code of 1986. Effective for the 5-year period beginning on the date of the enactment of this Act, such health plans

shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.

(2) EXISTING STATE LAWS.—A State law relating to payment for health preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 5-year period described in such paragraph unless the State reenacts such law after such period.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 201. APPLICATION TO CERTAIN HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

"SEC. 2707. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

"(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under title I of the Patients' Bill of Rights Act of 2001 with respect to non-Federal governmental group health insurance coverage offered by such issuers, and such requirements shall be deemed to be incorporated into this section.

"(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after the date of enactment of the Patients' Bill of Rights Act of 2001) shall apply to non-Federal governmental group health insurance coverage offered by health insurance issuers with respect to an enrollee in the same manner as they apply to health insurance coverage offered by a health insurance issuer for a participant or beneficiary in connection with a group health plan and the requirements referred to in such sections shall be deemed to be incorporated into this section. For purposes of this subsection, references in such sections 503 through 503B to the Secretary shall be deemed to be references to the Secretary of Health and Human Services.

''(c) CONSTRUCTION.—Nothing in this section shall be construed to affect section 2721(b)(2).''.

(b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting ''(other than section 2707)'' after ''requirements of such subparts''.

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–41 et seq.) is amended—

(1) by redesignating the first subpart 3 (relating to other requirements) as subpart 2; and

(2) by inserting after section 2752 the following:

''SEC. 2753. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

''(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under subtitles A and B of title I of the Patients' Bill of Rights Act of 2001 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this section.

''(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after the date of enactment of the Patients' Bill of Rights Act of 2001) shall apply to health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee in the same manner as they apply to health insurance coverage offered by a health insurance issuer for a participant or beneficiary in connection with a group health plan and the requirements referred to in such sections shall be deemed to be incorporated into this section. For purposes of this subsection, references in such sections 503 through 503B to the Secretary shall be deemed to be references to the Secretary of Health and Human Services.''.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is further amended by adding at the end the following new section:

"SEC. 714. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering health insurance coverage in connection with a group health plan) shall comply with the requirements of title I of the Patients' Bill of Rights Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Patients' Bill of Rights Act of 2001 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

"(A) Section 101 (relating to access to emergency care).

"(B) Section 102 (relating to consumer choice option).

"(C) Section 103 (relating to patient access to obstetric and gynecological care).

"(D) Section 104 (relating to access to pediatric care).

"(E) Section 105 (relating to timely access to specialists).

"(F) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

"(G) Section 108 (relating to access to needed prescription drugs).

"(H) Section 109 (relating to coverage for individuals participating in approved clinical trials).

"(I) Section 121 (relating to the provision of information).

"(2) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offering health insurance coverage in connection with a group health plan takes an action in violation of any of the following sections of the Patients' Bill of Rights Act of 2001, the group health plan shall not be liable for such violation unless the plan caused such violation:

"(A) Section 107 (relating to prohibition of interference with certain medical communications).

"(B) Section 110 (relating to prohibition of discrimination against providers based on licensure).

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(4) TREATMENT OF CONSISTENT STATE LAWS.—For purposes of applying this subsection, a health insurance issuer offering coverage in connection with a group health plan (and such group health plan) shall be deemed to be in compliance with one or more of the patient protection requirements of the Patients' Bill of Rights Act of 2001 (as defined in section 151(a)(1)(C) of such Act) that are

otherwise applicable to such issuer (or plan) under this section where the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified in accordance with section 151 of such Act.

''(c) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under the other provisions of this title.''.

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended—

(1) by inserting ''(a)'' after ''SEC. 503.''; and

(2) by adding at the end the following:

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle A of title I of the Patients' Bill of Rights Act of 2001, and compliance with regulations promulgated by the Secretary, in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(c) ENFORCEMENT.—Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended—

(1) by striking ''The Secretary'' and inserting ''(A) The Secretary''; and

(2) by adding at the end the following:

''(B) A participant, beneficiary, plan fiduciary, or the Secretary may not bring an action to enforce the requirements of section 714 against a health insurance issuer offering coverage in connection with a group health plan (or such group health plan) where the patient protection requirements of the Patients' Bill of Rights Act of 2001 (as defined in section 151(a)(1)(C) of such Act) otherwise applicable to such issuer (or plan) under section 714 do not apply because the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified

or a determination made in accordance with section 151 of such Act.''.

(d) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(2) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Patient protection standards.''.

(3) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by inserting ''(other than section 135(b))'' after ''part 7''.

(4) Section 731(a)(1) of such Act (29 U.S.C. 1191(a)(1)) is amended by inserting ''and section 151 of the Patients' Bill of Rights Act of 2001'' after ''Subject to paragraph (2)''.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

SEC. 401. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Standard relating to patients' bill of rights.'';

and

(2) by inserting after section 9812 the following:

''SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

''A group health plan shall comply with the requirements of subtitles A and B title I of the Patients' Bill of Rights Act of 2001 (and subtitle F of such title insofar as it applies to

such subtitles A and B) and of sections 503A and 503B of the Employee Retirement Income Security Act of 1974, as such requirements are in effect as of the date of the enactment of such Act, and such requirements shall be deemed to be incorporated into this section.''.

TITLE V—EFFECTIVE DATE; SEVERABILITY

SEC. 501. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—Except as otherwise provided in this Act, the provisions of this Act, including the amendments made by title I, shall apply—

(1) to group health plans, and health insurance coverage offered in connection with such plans, on the later of—

(A) plan years beginning on or after January 1 of the first calendar year that begins more than 1 year after the date of the enactment of this Act; or

(B) plan years beginning on or after 18 months after the date on which the Secretary of Health and Human Services and the Secretary of Labor issue final regulations, subject to the notice and comment period required under subchapter 2 of chapter 5 of title 5, United States Code, necessary to carry out such provisions and the amendments made by this Act; and

(2) to individual health insurance coverage beginning on or after the effective date described in paragraph (1)(A).

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this Act, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

(c) TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.—

(1) IN GENERAL.—Nothing in this Act (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers offering health insurance coverage, to include as providers religious nonmedical providers;

(B) require such plans or issuers to—

(i) utilize medically based eligibility standards or criteria in deciding provider status of religious nonmedical providers;

(ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;

(iii) utilize medical professionals or criteria in making determinations in internal or external appeals regarding coverage for care by religious nonmedical providers; or

(iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or

(C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the religious nonmedical treatment or nursing care provided by the provider.

(2) RELIGIOUS NONMEDICAL PROVIDER.—For purposes of this subsection, the term ''religious nonmedical provider'' means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

SEC. 502. SEVERABILITY.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), if any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and

the application of the provisions of such to any person or circumstance shall not be affected thereby.

(b) DEPENDENCE OF REMEDIES ON APPEALS.—If any provision of section 131, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, sections 141 and 142 and the amendments made by such sections, shall be deemed to be null and void and shall be given no force or effect.

(c) REMEDIES.—If any provision of section 141 or 142, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, the remainder of such section, and the amendments made by such section shall be deemed to be null and void and shall be given no force or effect.

TITLE VI—INCREASING ACCESS TO AFFORDABLE HEALTH INSURANCE

Subtitle A—Tax Incentives

SEC. 601. EXPANSION OF AVAILABILITY OF ARCHER MEDICAL SAVINGS ACCOUNTS.

(a) REPEAL OF LIMITATIONS ON NUMBER OF MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Subsections (i) and (j) of section 220 of the Internal Revenue Code of 1986 are hereby repealed.

(2) CONFORMING AMENDMENTS.—

(A) Paragraph (1) of section 220(c) of such Code is amended by striking subparagraph (D).

(B) Section 138 of such Code is amended by striking subsection (f).

(b) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR EMPLOYEES OF SMALL EMPLOYERS AND SELF-EMPLOYED INDIVIDUALS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(1) of such Code (relating to eligible individual) is amended to read as follows:

''(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

''(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

''(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

''(I) which is not a high deductible health plan, and

''(II) which provides coverage for any benefit which is covered under the high deductible health plan.''.

(2) CONFORMING AMENDMENTS.—

(A) Section 220(c)(1) of such Code is amended by striking subparagraph (C).

(B) Section 220(c) of such Code is amended by striking paragraph (4) (defining small employer) and by redesignating paragraph (5) as paragraph (4).

(C) Section 220(b) of such Code is amended by striking paragraph (4) (relating to deduction limited by compensation) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(c) INCREASE IN AMOUNT OF DEDUCTION ALLOWED FOR CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Paragraph (2) of section 220(b) of such Code is amended to read as follows:

''(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to 1/12 of the annual deductible (as of the first day of such month) of the individual's coverage under the high deductible health plan.''.

(2) CONFORMING AMENDMENT.—Clause (ii) of section 220(d)(1)(A) of such Code is amended by striking ''75 percent of''.

(d) BOTH EMPLOYERS AND EMPLOYEES MAY CONTRIBUTE TO MEDICAL SAVINGS ACCOUNTS.—Paragraph (4) of

section 220(b) of such Code (as redesignated by subsection (b)(2)(C)) is amended to read as follows:

''(4) COORDINATION WITH EXCLUSION FOR EMPLOYER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under this subsection to the taxpayer for any taxable year shall be reduced (but not below zero) by the amount which would (but for section 106(b)) be includible in the taxpayer's gross income for such taxable year.''.

(e) REDUCTION OF PERMITTED DEDUCTIBLES UNDER HIGH DEDUCTIBLE HEALTH PLANS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of such Code (defining high deductible health plan) is amended—

(A) by striking ''$1,500'' in clause (i) and inserting ''$1,000''; and

(B) by striking ''$3,000'' in clause (ii) and inserting ''$2,000''.

(2) CONFORMING AMENDMENT.—Subsection (g) of section 220 of such Code is amended to read as follows:

''(g) COST-OF-LIVING ADJUSTMENT.—

''(1) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 1998, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

''(A) such dollar amount, multiplied by

''(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting 'calendar year 1997' for 'calendar year 1992' in subparagraph (B) thereof.

''(2) SPECIAL RULES.—In the case of the $1,000 amount in subsection (c)(2)(A)(i) and the $2,000 amount in subsection (c)(2)(A)(ii), paragraph (1)(B) shall be applied by substituting 'calendar year 2000' for 'calendar year 1997'.

''(3) ROUNDING.—If any increase under paragraph (1) or (2) is not a multiple of $50, such increase shall be rounded to the nearest multiple of $50.''.

(f) PROVIDING INCENTIVES FOR PREFERRED PROVIDER ORGANIZATIONS TO OFFER MEDICAL SAVINGS ACCOUNTS.—Clause (ii) of section 220(c)(2)(B) of such Code is amended by striking ''preventive care if'' and all that follows and inserting ''preventive care.''

(g) MEDICAL SAVINGS ACCOUNTS MAY BE OFFERED UNDER CAFETERIA PLANS.—Subsection (f) of section 125 of such Code is amended by striking ''106(b),''.

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

Subtitle B—Association Health Plans

SEC. 621. RULES GOVERNING ASSOCIATION HEALTH PLANS.

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding after part 7 the following new part:

''PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

''SEC. 801. ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—For purposes of this part, the term 'association health plan' means a group health plan whose sponsor is (or is deemed under this part to be) described in subsection (b).

''(b) SPONSORSHIP.—The sponsor of a group health plan is described in this subsection if such sponsor—

''(1) is organized and maintained in good faith, with a constitution and bylaws specifically stating its purpose and providing for periodic meetings on at least an annual basis, as a bona fide trade association, a bona fide industry association (including a rural electric cooperative association or a rural telephone cooperative association), a bona fide professional association, or a bona fide chamber of commerce (or similar bona fide business association, including a corporation or similar organization that operates on

a cooperative basis (within the meaning of section 1381 of the Internal Revenue Code of 1986)), for substantial purposes other than that of obtaining or providing medical care;

''(2) is established as a permanent entity which receives the active support of its members and collects from its members on a periodic basis dues or payments necessary to maintain eligibility for membership in the sponsor; and

''(3) does not condition membership, such dues or payments, or coverage under the plan on the basis of health status-related factors with respect to the employees of its members (or affiliated members), or the dependents of such employees, and does not condition such dues or payments on the basis of group health plan participation.

Any sponsor consisting of an association of entities which meet the requirements of paragraphs (1), (2), and (3) shall be deemed to be a sponsor described in this subsection.

''SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—The applicable authority shall prescribe by regulation, through negotiated rulemaking, a procedure under which, subject to subsection (b), the applicable authority shall certify association health plans which apply for certification as meeting the requirements of this part.

''(b) STANDARDS.—Under the procedure prescribed pursuant to subsection (a), in the case of an association health plan that provides at least one benefit option which does not consist of health insurance coverage, the applicable authority shall certify such plan as meeting the requirements of this part only if the applicable authority is satisfied that the applicable requirements of this part are met (or, upon the date on which the plan is to commence operations, will be met) with respect to the plan.

''(c) REQUIREMENTS APPLICABLE TO CERTIFIED PLANS.—An association health plan with respect to which certification under this part is in effect shall meet the applicable requirements of this part, effective on the date of certification

(or, if later, on the date on which the plan is to commence operations).

"(d) REQUIREMENTS FOR CONTINUED CERTIFICATION.—The applicable authority may provide by regulation, through negotiated rulemaking, for continued certification of association health plans under this part.

"(e) CLASS CERTIFICATION FOR FULLY INSURED PLANS.—The applicable authority shall establish a class certification procedure for association health plans under which all benefits consist of health insurance coverage. Under such procedure, the applicable authority shall provide for the granting of certification under this part to the plans in each class of such association health plans upon appropriate filing under such procedure in connection with plans in such class and payment of the prescribed fee under section 807(a).

"(f) CERTIFICATION OF SELF-INSURED ASSOCIATION HEALTH PLANS.—An association health plan which offers one or more benefit options which do not consist of health insurance coverage may be certified under this part only if such plan consists of any of the following:

"(1) a plan which offered such coverage on the date of the enactment of the Patients' Bill of Rights Act of 2001,

"(2) a plan under which the sponsor does not restrict membership to one or more trades and businesses or industries and whose eligible participating employers represent a broad cross-section of trades and businesses or industries, or

"(3) a plan whose eligible participating employers represent one or more trades or businesses, or one or more industries, which have been indicated as having average or above-average health insurance risk or health claims experience by reason of State rate filings, denials of coverage, proposed premium rate levels, and other means demonstrated by such plan in accordance with regulations which the Secretary shall prescribe through negotiated rulemaking, including (but not limited to) the following: agri-

culture; equipment and automobile dealerships; barbering and cosmetology; beverage wholesaling/distributing; certified public accounting practices; child care; construction; dance, theatrical, and orchestra productions; disinfecting and pest control; eating and drinking establishments; fishing; hospitals; labor organizations; logging; manufacturing (metals); mining; medical and dental practices; medical laboratories; sanitary services; transportation (local and freight); and warehousing.

"SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND BOARDS OF TRUSTEES.

"(a) SPONSOR.—The requirements of this subsection are met with respect to an association health plan if the sponsor has met (or is deemed under this part to have met) the requirements of section 801(b) for a continuous period of not less than 3 years ending with the date of the application for certification under this part.

"(b) BOARD OF TRUSTEES.—The requirements of this subsection are met with respect to an association health plan if the following requirements are met:

"(1) FISCAL CONTROL.—The plan is operated, pursuant to a trust agreement, by a board of trustees which has complete fiscal control over the plan and which is responsible for all operations of the plan.

"(2) RULES OF OPERATION AND FINANCIAL CONTROLS.—The board of trustees has in effect rules of operation and financial controls, based on a 3-year plan of operation, adequate to carry out the terms of the plan and to meet all requirements of this title applicable to the plan.

"(3) RULES GOVERNING RELATIONSHIP TO PARTICIPATING EMPLOYERS AND TO CONTRACTORS.—

"(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the members of the board of trustees are individuals selected from individuals who are the owners, officers, directors, or employees of the participating employers or who are partners in the par-

ticipating employers and actively participate in the business.

"(B) LIMITATION.—

"(i) GENERAL RULE.—Except as provided in clauses (ii) and (iii), no such member is an owner, officer, director, or employee of, or partner in, a contract administrator or other service provider to the plan.

"(ii) LIMITED EXCEPTION FOR PROVIDERS OF SERVICES SOLELY ON BEHALF OF THE SPONSOR.—Officers or employees of a sponsor which is a service provider (other than a contract administrator) to the plan may be members of the board if they constitute not more than 25 percent of the membership of the board and they do not provide services to the plan other than on behalf of the sponsor.

"(iii) TREATMENT OF PROVIDERS OF MEDICAL CARE.—In the case of a sponsor which is an association whose membership consists primarily of providers of medical care, clause (i) shall not apply in the case of any service provider described in subparagraph (A) who is a provider of medical care under the plan.

"(C) CERTAIN PLANS EXCLUDED.—Subparagraph (A) shall not apply to an association health plan which is in existence on the date of the enactment of the Patients' Bill of Rights Act of 2001.

"(D) SOLE AUTHORITY.—The board has sole authority under the plan to approve applications for participation in the plan and to contract with a service provider to administer the day-to-day affairs of the plan.

"(c) TREATMENT OF FRANCHISE NETWORKS.—In the case of a group health plan which is established and maintained by a franchiser for a franchise network consisting of its franchisees—

"(1) the requirements of subsection (a) and section 801(a)(1) shall be deemed met if such requirements would otherwise be met if the franchiser were deemed to be the sponsor referred to in section 801(b), such network were deemed to be an association described in section 801(b), and each franchisee were deemed to be a member (of the association and the sponsor) referred to in section 801(b); and

"(2) the requirements of section 804(a)(1) shall be deemed met.

The Secretary may by regulation, through negotiated rulemaking, define for purposes of this subsection the terms 'franchiser', 'franchise network', and 'franchisee'.

"(d) CERTAIN COLLECTIVELY BARGAINED PLANS.—

"(1) IN GENERAL.—In the case of a group health plan described in paragraph (2)—

"(A) the requirements of subsection (a) and section 801(a)(1) shall be deemed met;

"(B) the joint board of trustees shall be deemed a board of trustees with respect to which the requirements of subsection (b) are met; and

"(C) the requirements of section 804 shall be deemed met.

"(2) REQUIREMENTS.—A group health plan is described in this paragraph if—

"(A) the plan is a multiemployer plan; or

"(B) the plan is in existence on April 1, 2001, and would be described in section 3(40)(A)(i) but solely for the failure to meet the requirements of section 3(40)(C)(ii).

"SEC. 804. PARTICIPATION AND COVERAGE REQUIREMENTS.

"(a) COVERED EMPLOYERS AND INDIVIDUALS.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan—

"(1) each participating employer must be—

"(A) a member of the sponsor,

"(B) the sponsor, or

"(C) an affiliated member of the sponsor with respect to which the requirements of subsection (b) are met,

except that, in the case of a sponsor which is a professional association or other individual-based association, if at least one of the officers, directors, or employees of an employer, or at least one of the individuals who are partners in an employer and who actively participates in the business, is a member or such an affiliated member of the sponsor, participating employers may also include such employer; and

"(2) all individuals commencing coverage under the plan after certification under this part must be—

"(A) active or retired owners (including self-employed individuals), officers, directors, or employees of, or partners in, participating employers; or

"(B) the beneficiaries of individuals described in subparagraph (A).

"(b) COVERAGE OF PREVIOUSLY UNINSURED EMPLOYEES.—In the case of an association health plan in existence on the date of the enactment of the Patients' Bill of Rights Act of 2001, an affiliated member of the sponsor of the plan may be offered coverage under the plan as a participating employer only if—

"(1) the affiliated member was an affiliated member on the date of certification under this part; or

"(2) during the 12-month period preceding the date of the offering of such coverage, the affiliated member has not maintained or contributed to a group health plan with respect to any of its employees who would otherwise be eligible to participate in such association health plan.

"(c) INDIVIDUAL MARKET UNAFFECTED.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan, no participating employer may provide health insurance coverage in the individual market for any employee not covered under the plan which is similar to the coverage contemporaneously provided to

employees of the employer under the plan, if such exclusion of the employee from coverage under the plan is based on a health status-related factor with respect to the employee and such employee would, but for such exclusion on such basis, be eligible for coverage under the plan.

''(d) PROHIBITION OF DISCRIMINATION AGAINST EMPLOYERS AND EMPLOYEES ELIGIBLE TO PARTICIPATE.—The requirements of this subsection are met with respect to an association health plan if—

''(1) under the terms of the plan, all employers meeting the preceding requirements of this section are eligible to qualify as participating employers for all geographically available coverage options, unless, in the case of any such employer, participation or contribution requirements of the type referred to in section 2711 of the Public Health Service Act are not met;

''(2) upon request, any employer eligible to participate is furnished information regarding all coverage options available under the plan; and

''(3) the applicable requirements of sections 701, 702, and 703 are met with respect to the plan.

''SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN DOCUMENTS, CONTRIBUTION RATES, AND BENEFIT OPTIONS.

''(a) IN GENERAL.—The requirements of this section are met with respect to an association health plan if the following requirements are met:

''(1) CONTENTS OF GOVERNING INSTRUMENTS.—The instruments governing the plan include a written instrument, meeting the requirements of an instrument required under section 402(a)(1), which—

''(A) provides that the board of trustees serves as the named fiduciary required for plans under section 402(a)(1) and serves in the capacity of a plan administrator (referred to in section 3(16)(A));

"(B) provides that the sponsor of the plan is to serve as plan sponsor (referred to in section 3(16)(B)); and

"(C) incorporates the requirements of section 806.

"(2) CONTRIBUTION RATES MUST BE NONDISCRIMINATORY.—

"(A) The contribution rates for any participating small employer do not vary on the basis of the claims experience of such employer and do not vary on the basis of the type of business or industry in which such employer is engaged.

"(B) Nothing in this title or any other provision of law shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from—

"(i) setting contribution rates based on the claims experience of the plan; or

"(ii) varying contribution rates for small employers in a State to the extent that such rates could vary using the same methodology employed in such State for regulating premium rates in the small group market with respect to health insurance coverage offered in connection with bona fide associations (within the meaning of section 2791(d)(3) of the Public Health Service Act),

subject to the requirements of section 702(b) relating to contribution rates.

"(3) FLOOR FOR NUMBER OF COVERED INDIVIDUALS WITH RESPECT TO CERTAIN PLANS.—If any benefit option under the plan does not consist of health insurance coverage, the plan has as of the beginning of the plan year not fewer than 1,000 participants and beneficiaries.

"(4) MARKETING REQUIREMENTS.—

"(A) IN GENERAL.—If a benefit option which consists of health insurance coverage is offered under the plan, State-licensed insurance agents shall be used to

distribute to small employers coverage which does not consist of health insurance coverage in a manner comparable to the manner in which such agents are used to distribute health insurance coverage.

"(B) STATE-LICENSED INSURANCE AGENTS.—For purposes of subparagraph (A), the term 'State-licensed insurance agents' means one or more agents who are licensed in a State and are subject to the laws of such State relating to licensure, qualification, testing, examination, and continuing education of persons authorized to offer, sell, or solicit health insurance coverage in such State.

"(5) REGULATORY REQUIREMENTS.—Such other requirements as the applicable authority determines are necessary to carry out the purposes of this part, which shall be prescribed by the applicable authority by regulation through negotiated rulemaking.

"(b) ABILITY OF ASSOCIATION HEALTH PLANS TO DESIGN BENEFIT OPTIONS.—Subject to section 514(e), nothing in this part or any provision of State law (as defined in section 514(c)(1)) shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from exercising its sole discretion in selecting the specific items and services consisting of medical care to be included as benefits under such plan or coverage, except (subject to section 514) in the case of any law to the extent that it (1) prohibits an exclusion of a specific disease from such coverage, or (2) is not preempted under section 731(a)(1) with respect to matters governed by section 711 or 712.

"SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS FOR SOLVENCY FOR PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

"(a) IN GENERAL.—The requirements of this section are met with respect to an association health plan if—

"(1) the benefits under the plan consist solely of health insurance coverage; or

"(2) if the plan provides any additional benefit options which do not consist of health insurance coverage, the plan—

"(A) establishes and maintains reserves with respect to such additional benefit options, in amounts recommended by the qualified actuary, consisting of—

"(i) a reserve sufficient for unearned contributions;

"(ii) a reserve sufficient for benefit liabilities which have been incurred, which have not been satisfied, and for which risk of loss has not yet been transferred, and for expected administrative costs with respect to such benefit liabilities;

"(iii) a reserve sufficient for any other obligations of the plan; and

"(iv) a reserve sufficient for a margin of error and other fluctuations, taking into account the specific circumstances of the plan; and

"(B) establishes and maintains aggregate and specific excess/stop loss insurance and solvency indemnification, with respect to such additional benefit options for which risk of loss has not yet been transferred, as follows:

"(i) The plan shall secure aggregate excess/stop loss insurance for the plan with an attachment point which is not greater than 125 percent of expected gross annual claims. The applicable authority may by regulation, through negotiated rulemaking, provide for upward adjustments in the amount of such percentage in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

"(ii) The plan shall secure specific excess/stop loss insurance for the plan with an attachment

point which is at least equal to an amount recommended by the plan's qualified actuary. The applicable authority may by regulation, through negotiated rulemaking, provide for adjustments in the amount of such insurance in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

"(iii) The plan shall secure indemnification insurance for any claims which the plan is unable to satisfy by reason of a plan termination.

Any regulations prescribed by the applicable authority pursuant to clause (i) or (ii) of subparagraph (B) may allow for such adjustments in the required levels of excess/stop loss insurance as the qualified actuary may recommend, taking into account the specific circumstances of the plan.

"(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS RESERVES.—In the case of any association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan establishes and maintains surplus in an amount at least equal to—

"(1) $500,000, or

"(2) such greater amount (but not greater than $2,000,000) as may be set forth in regulations prescribed by the applicable authority through negotiated rulemaking, based on the level of aggregate and specific excess/stop loss insurance provided with respect to such plan.

"(c) ADDITIONAL REQUIREMENTS.—In the case of any association health plan described in subsection (a)(2), the applicable authority may provide such additional requirements relating to reserves and excess/stop loss insurance as the applicable authority considers appropriate. Such requirements may be provided by regulation, through negotiated rulemaking, with respect to any such plan or any class of such plans.

"(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSURANCE.—The applicable authority may provide for adjustments to the levels of reserves otherwise required under subsections

(a) and (b) with respect to any plan or class of plans to take into account excess/stop loss insurance provided with respect to such plan or plans.

"(e) ALTERNATIVE MEANS OF COMPLIANCE.—The applicable authority may permit an association health plan described in subsection (a)(2) to substitute, for all or part of the requirements of this section (except subsection (a)(2)(B)(iii)), such security, guarantee, hold-harmless arrangement, or other financial arrangement as the applicable authority determines to be adequate to enable the plan to fully meet all its financial obligations on a timely basis and is otherwise no less protective of the interests of participants and beneficiaries than the requirements for which it is substituted. The applicable authority may take into account, for purposes of this subsection, evidence provided by the plan or sponsor which demonstrates an assumption of liability with respect to the plan. Such evidence may be in the form of a contract of indemnification, lien, bonding, insurance, letter of credit, recourse under applicable terms of the plan in the form of assessments of participating employers, security, or other financial arrangement.

"(f) MEASURES TO ENSURE CONTINUED PAYMENT OF BENEFITS BY CERTAIN PLANS IN DISTRESS.—

"(1) PAYMENTS BY CERTAIN PLANS TO ASSOCIATION HEALTH PLAN FUND.—

"(A) IN GENERAL.—In the case of an association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan makes payments into the Association Health Plan Fund under this subparagraph when they are due. Such payments shall consist of annual payments in the amount of $5,000, and, in addition to such annual payments, such supplemental payments as the Secretary may determine to be necessary under paragraph (2). Payments under this paragraph are payable to the Fund at the time determined by the Secretary. Initial payments are due in advance of certification under this part. Payments shall

continue to accrue until a plan's assets are distributed pursuant to a termination procedure.

"(B) PENALTIES FOR FAILURE TO MAKE PAYMENTS.—If any payment is not made by a plan when it is due, a late payment charge of not more than 100 percent of the payment which was not timely paid shall be payable by the plan to the Fund.

"(C) CONTINUED DUTY OF THE SECRETARY.—The Secretary shall not cease to carry out the provisions of paragraph (2) on account of the failure of a plan to pay any payment when due.

"(2) PAYMENTS BY SECRETARY TO CONTINUE EXCESS/STOP LOSS INSURANCE COVERAGE AND INDEMNIFICATION INSURANCE COVERAGE FOR CERTAIN PLANS.—In any case in which the applicable authority determines that there is, or that there is reason to believe that there will be: (A) a failure to take necessary corrective actions under section 809(a) with respect to an association health plan described in subsection (a)(2); or (B) a termination of such a plan under section 809(b) or 810(b)(8) (and, if the applicable authority is not the Secretary, certifies such determination to the Secretary), the Secretary shall determine the amounts necessary to make payments to an insurer (designated by the Secretary) to maintain in force excess/stop loss insurance coverage or indemnification insurance coverage for such plan, if the Secretary determines that there is a reasonable expectation that, without such payments, claims would not be satisfied by reason of termination of such coverage. The Secretary shall, to the extent provided in advance in appropriation Acts, pay such amounts so determined to the insurer designated by the Secretary.

"(3) ASSOCIATION HEALTH PLAN FUND.—

"(A) IN GENERAL.—There is established on the books of the Treasury a fund to be known as the 'Association Health Plan Fund'. The Fund shall be available for making payments pursuant to paragraph (2). The Fund shall be credited with payments received pursu-

ant to paragraph (1)(A), penalties received pursuant to paragraph (1)(B); and earnings on investments of amounts of the Fund under subparagraph (B).

''(B) INVESTMENT.—Whenever the Secretary determines that the moneys of the fund are in excess of current needs, the Secretary may request the investment of such amounts as the Secretary determines advisable by the Secretary of the Treasury in obligations issued or guaranteed by the United States.

''(g) EXCESS/STOP LOSS INSURANCE.—For purposes of this section—

''(1) AGGREGATE EXCESS/STOP LOSS INSURANCE.—The term 'aggregate excess/stop loss insurance' means, in connection with an association health plan, a contract—

''(A) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation through negotiated rulemaking) provides for payment to the plan with respect to aggregate claims under the plan in excess of an amount or amounts specified in such contract;

''(B) which is guaranteed renewable; and

''(C) which allows for payment of premiums by any third party on behalf of the insured plan.

''(2) SPECIFIC EXCESS/STOP LOSS INSURANCE.—The term 'specific excess/stop loss insurance' means, in connection with an association health plan, a contract—

''(A) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation through negotiated rulemaking) provides for payment to the plan with respect to claims under the plan in connection with a covered individual in excess of an amount or amounts specified in such contract in connection with such covered individual;

''(B) which is guaranteed renewable; and

''(C) which allows for payment of premiums by any third party on behalf of the insured plan.

"(h) INDEMNIFICATION INSURANCE.—For purposes of this section, the term 'indemnification insurance' means, in connection with an association health plan, a contract—

"(1) under which an insurer (meeting such minimum standards as the applicable authority may prescribe through negotiated rulemaking) provides for payment to the plan with respect to claims under the plan which the plan is unable to satisfy by reason of a termination pursuant to section 809(b) (relating to mandatory termination);

"(2) which is guaranteed renewable and noncancellable for any reason (except as the applicable authority may prescribe by regulation through negotiated rulemaking); and

"(3) which allows for payment of premiums by any third party on behalf of the insured plan.

"(i) RESERVES.—For purposes of this section, the term 'reserves' means, in connection with an association health plan, plan assets which meet the fiduciary standards under part 4 and such additional requirements regarding liquidity as the applicable authority may prescribe through negotiated rulemaking.

"(j) SOLVENCY STANDARDS WORKING GROUP.—

"(1) IN GENERAL.—Within 90 days after the date of the enactment of the Patients' Bill of Rights Act of 2001, the applicable authority shall establish a Solvency Standards Working Group. In prescribing the initial regulations under this section, the applicable authority shall take into account the recommendations of such Working Group.

"(2) MEMBERSHIP.—The Working Group shall consist of not more than 15 members appointed by the applicable authority. The applicable authority shall include among persons invited to membership on the Working Group at least one of each of the following:

"(A) a representative of the National Association of Insurance Commissioners;

"(B) a representative of the American Academy of Actuaries;

"(C) a representative of the State governments, or their interests;

"(D) a representative of existing self-insured arrangements, or their interests;

"(E) a representative of associations of the type referred to in section 801(b)(1), or their interests; and

"(F) a representative of multiemployer plans that are group health plans, or their interests.

"SEC. 807. REQUIREMENTS FOR APPLICATION AND RELATED REQUIREMENTS.

"(a) FILING FEE.—Under the procedure prescribed pursuant to section 802(a), an association health plan shall pay to the applicable authority at the time of filing an application for certification under this part a filing fee in the amount of $5,000, which shall be available in the case of the Secretary, to the extent provided in appropriation Acts, for the sole purpose of administering the certification procedures applicable with respect to association health plans.

"(b) INFORMATION TO BE INCLUDED IN APPLICATION FOR CERTIFICATION.—An application for certification under this part meets the requirements of this section only if it includes, in a manner and form which shall be prescribed by the applicable authority through negotiated rulemaking, at least the following information:

"(1) IDENTIFYING INFORMATION.—The names and addresses of—

"(A) the sponsor; and

"(B) the members of the board of trustees of the plan.

"(2) STATES IN WHICH PLAN INTENDS TO DO BUSINESS.—The States in which participants and beneficiaries under the plan are to be located and the number of them expected to be located in each such State.

"(3) BONDING REQUIREMENTS.—Evidence provided by the board of trustees that the bonding requirements of section 412 will be met as of the date of the application or (if later) commencement of operations.

"(4) PLAN DOCUMENTS.—A copy of the documents governing the plan (including any bylaws and trust agreements), the summary plan description, and other material describing the benefits that will be provided to participants and beneficiaries under the plan.

"(5) AGREEMENTS WITH SERVICE PROVIDERS.—A copy of any agreements between the plan and contract administrators and other service providers.

"(6) FUNDING REPORT.—In the case of association health plans providing benefits options in addition to health insurance coverage, a report setting forth information with respect to such additional benefit options determined as of a date within the 120-day period ending with the date of the application, including the following:

"(A) RESERVES.—A statement, certified by the board of trustees of the plan, and a statement of actuarial opinion, signed by a qualified actuary, that all applicable requirements of section 806 are or will be met in accordance with regulations which the applicable authority shall prescribe through negotiated rulemaking.

"(B) ADEQUACY OF CONTRIBUTION RATES.—A statement of actuarial opinion, signed by a qualified actuary, which sets forth a description of the extent to which contribution rates are adequate to provide for the payment of all obligations and the maintenance of required reserves under the plan for the 12-month period beginning with such date within such 120-day period, taking into account the expected coverage and experience of the plan. If the contribution rates are not fully adequate, the statement of actuarial opinion shall indicate the extent to which the rates are inadequate and the changes needed to ensure adequacy.

"(C) CURRENT AND PROJECTED VALUE OF ASSETS AND LIABILITIES.—A statement of actuarial opinion signed by a qualified actuary, which sets forth the current value of the assets and liabilities accumulated under the plan and a projection of the assets, liabilities,

income, and expenses of the plan for the 12-month period referred to in subparagraph (B). The income statement shall identify separately the plan's administrative expenses and claims.

"(D) COSTS OF COVERAGE TO BE CHARGED AND OTHER EXPENSES.—A statement of the costs of coverage to be charged, including an itemization of amounts for administration, reserves, and other expenses associated with the operation of the plan.

"(E) OTHER INFORMATION.—Any other information as may be determined by the applicable authority, by regulation through negotiated rulemaking, as necessary to carry out the purposes of this part.

"(c) FILING NOTICE OF CERTIFICATION WITH STATES.—A certification granted under this part to an association health plan shall not be effective unless written notice of such certification is filed with the applicable State authority of each State in which at least 25 percent of the participants and beneficiaries under the plan are located. For purposes of this subsection, an individual shall be considered to be located in the State in which a known address of such individual is located or in which such individual is employed.

"(d) NOTICE OF MATERIAL CHANGES.—In the case of any association health plan certified under this part, descriptions of material changes in any information which was required to be submitted with the application for the certification under this part shall be filed in such form and manner as shall be prescribed by the applicable authority by regulation through negotiated rulemaking. The applicable authority may require by regulation, through negotiated rulemaking, prior notice of material changes with respect to specified matters which might serve as the basis for suspension or revocation of the certification.

"(e) REPORTING REQUIREMENTS FOR CERTAIN ASSOCIATION HEALTH PLANS.—An association health plan certified under this part which provides benefit options in addition to health insurance coverage for such plan year shall meet the requirements of section 103 by filing an annual report under

such section which shall include information described in subsection (b)(6) with respect to the plan year and, notwithstanding section 104(a)(1)(A), shall be filed with the applicable authority not later than 90 days after the close of the plan year (or on such later date as may be prescribed by the applicable authority). The applicable authority may require by regulation through negotiated rulemaking such interim reports as it considers appropriate.

''(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The board of trustees of each association health plan which provides benefits options in addition to health insurance coverage and which is applying for certification under this part or is certified under this part shall engage, on behalf of all participants and beneficiaries, a qualified actuary who shall be responsible for the preparation of the materials comprising information necessary to be submitted by a qualified actuary under this part. The qualified actuary shall utilize such assumptions and techniques as are necessary to enable such actuary to form an opinion as to whether the contents of the matters reported under this part—

''(1) are in the aggregate reasonably related to the experience of the plan and to reasonable expectations; and

''(2) represent such actuary's best estimate of anticipated experience under the plan.

The opinion by the qualified actuary shall be made with respect to, and shall be made a part of, the annual report.

''SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TERMINATION.

''Except as provided in section 809(b), an association health plan which is or has been certified under this part may terminate (upon or at any time after cessation of accruals in benefit liabilities) only if the board of trustees—

''(1) not less than 60 days before the proposed termination date, provides to the participants and beneficiaries a written notice of intent to terminate stating that such termination is intended and the proposed termination date;

"(2) develops a plan for winding up the affairs of the plan in connection with such termination in a manner which will result in timely payment of all benefits for which the plan is obligated; and

"(3) submits such plan in writing to the applicable authority.

Actions required under this section shall be taken in such form and manner as may be prescribed by the applicable authority by regulation through negotiated rulemaking.

"SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMINATION.

"(a) ACTIONS TO AVOID DEPLETION OF RESERVES.—An association health plan which is certified under this part and which provides benefits other than health insurance coverage shall continue to meet the requirements of section 806, irrespective of whether such certification continues in effect. The board of trustees of such plan shall determine quarterly whether the requirements of section 806 are met. In any case in which the board determines that there is reason to believe that there is or will be a failure to meet such requirements, or the applicable authority makes such a determination and so notifies the board, the board shall immediately notify the qualified actuary engaged by the plan, and such actuary shall, not later than the end of the next following month, make such recommendations to the board for corrective action as the actuary determines necessary to ensure compliance with section 806. Not later than 30 days after receiving from the actuary recommendations for corrective actions, the board shall notify the applicable authority (in such form and manner as the applicable authority may prescribe by regulation through negotiated rulemaking) of such recommendations of the actuary for corrective action, together with a description of the actions (if any) that the board has taken or plans to take in response to such recommendations. The board shall thereafter report to the applicable authority, in such form and frequency as the applicable authority may specify to the board, regarding corrective action

taken by the board until the requirements of section 806 are met.

''(b) MANDATORY TERMINATION.—In any case in which—

''(1) the applicable authority has been notified under subsection (a) of a failure of an association health plan which is or has been certified under this part and is described in section 806(a)(2) to meet the requirements of section 806 and has not been notified by the board of trustees of the plan that corrective action has restored compliance with such requirements; and

''(2) the applicable authority determines that there is a reasonable expectation that the plan will continue to fail to meet the requirements of section 806,

the board of trustees of the plan shall, at the direction of the applicable authority, terminate the plan and, in the course of the termination, take such actions as the applicable authority may require, including satisfying any claims referred to in section 806(a)(2)(B)(iii) and recovering for the plan any liability under subsection (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure that the affairs of the plan will be, to the maximum extent possible, wound up in a manner which will result in timely provision of all benefits for which the plan is obligated.

''SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOLVENT ASSOCIATION HEALTH PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

''(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR INSOLVENT PLANS.—Whenever the Secretary determines that an association health plan which is or has been certified under this part and which is described in section 806(a)(2) will be unable to provide benefits when due or is otherwise in a financially hazardous condition, as shall be defined by the Secretary by regulation through negotiated rulemaking, the Secretary shall, upon notice to the plan, apply to the appropriate United States district court for appointment of the Secretary as trustee to administer the plan for the duration of the insolvency. The plan

may appear as a party and other interested persons may intervene in the proceedings at the discretion of the court. The court shall appoint such Secretary trustee if the court determines that the trusteeship is necessary to protect the interests of the participants and beneficiaries or providers of medical care or to avoid any unreasonable deterioration of the financial condition of the plan. The trusteeship of such Secretary shall continue until the conditions described in the first sentence of this subsection are remedied or the plan is terminated.

''(b) POWERS AS TRUSTEE.—The Secretary, upon appointment as trustee under subsection (a), shall have the power—

''(1) to do any act authorized by the plan, this title, or other applicable provisions of law to be done by the plan administrator or any trustee of the plan;

''(2) to require the transfer of all (or any part) of the assets and records of the plan to the Secretary as trustee;

''(3) to invest any assets of the plan which the Secretary holds in accordance with the provisions of the plan, regulations prescribed by the Secretary through negotiated rulemaking, and applicable provisions of law;

''(4) to require the sponsor, the plan administrator, any participating employer, and any employee organization representing plan participants to furnish any information with respect to the plan which the Secretary as trustee may reasonably need in order to administer the plan;

''(5) to collect for the plan any amounts due the plan and to recover reasonable expenses of the trusteeship;

''(6) to commence, prosecute, or defend on behalf of the plan any suit or proceeding involving the plan;

''(7) to issue, publish, or file such notices, statements, and reports as may be required by the Secretary by regulation through negotiated rulemaking or required by any order of the court;

''(8) to terminate the plan (or provide for its termination in accordance with section 809(b)) and liquidate the

plan assets, to restore the plan to the responsibility of the sponsor, or to continue the trusteeship;

"(9) to provide for the enrollment of plan participants and beneficiaries under appropriate coverage options; and

"(10) to do such other acts as may be necessary to comply with this title or any order of the court and to protect the interests of plan participants and beneficiaries and providers of medical care.

"(c) NOTICE OF APPOINTMENT.—As soon as practicable after the Secretary's appointment as trustee, the Secretary shall give notice of such appointment to—

"(1) the sponsor and plan administrator;

"(2) each participant;

"(3) each participating employer; and

"(4) if applicable, each employee organization which, for purposes of collective bargaining, represents plan participants.

"(d) ADDITIONAL DUTIES.—Except to the extent inconsistent with the provisions of this title, or as may be otherwise ordered by the court, the Secretary, upon appointment as trustee under this section, shall be subject to the same duties as those of a trustee under section 704 of title 11, United States Code, and shall have the duties of a fiduciary for purposes of this title.

"(e) OTHER PROCEEDINGS.—An application by the Secretary under this subsection may be filed notwithstanding the pendency in the same or any other court of any bankruptcy, mortgage foreclosure, or equity receivership proceeding, or any proceeding to reorganize, conserve, or liquidate such plan or its property, or any proceeding to enforce a lien against property of the plan.

"(f) JURISDICTION OF COURT.—

"(1) IN GENERAL.—Upon the filing of an application for the appointment as trustee or the issuance of a decree under this section, the court to which the application is made shall have exclusive jurisdiction of the plan involved and its property wherever located with the powers, to the

extent consistent with the purposes of this section, of a court of the United States having jurisdiction over cases under chapter 11 of title 11, United States Code. Pending an adjudication under this section such court shall stay, and upon appointment by it of the Secretary as trustee, such court shall continue the stay of, any pending mortgage foreclosure, equity receivership, or other proceeding to reorganize, conserve, or liquidate the plan, the sponsor, or property of such plan or sponsor, and any other suit against any receiver, conservator, or trustee of the plan, the sponsor, or property of the plan or sponsor. Pending such adjudication and upon the appointment by it of the Secretary as trustee, the court may stay any proceeding to enforce a lien against property of the plan or the sponsor or any other suit against the plan or the sponsor.

''(2) VENUE.—An action under this section may be brought in the judicial district where the sponsor or the plan administrator resides or does business or where any asset of the plan is situated. A district court in which such action is brought may issue process with respect to such action in any other judicial district.

''(g) PERSONNEL.—In accordance with regulations which shall be prescribed by the Secretary through negotiated rulemaking, the Secretary shall appoint, retain, and compensate accountants, actuaries, and other professional service personnel as may be necessary in connection with the Secretary's service as trustee under this section.

''SEC. 811. STATE ASSESSMENT AUTHORITY.

''(a) IN GENERAL.—Notwithstanding section 514, a State may impose by law a contribution tax on an association health plan described in section 806(a)(2), if the plan commenced operations in such State after the date of the enactment of the Patients' Bill of Rights Act of 2001.

''(b) CONTRIBUTION TAX.—For purposes of this section, the term 'contribution tax' imposed by a State on an association health plan means any tax imposed by such State if—

"(1) such tax is computed by applying a rate to the amount of premiums or contributions, with respect to individuals covered under the plan who are residents of such State, which are received by the plan from participating employers located in such State or from such individuals;

"(2) the rate of such tax does not exceed the rate of any tax imposed by such State on premiums or contributions received by insurers or health maintenance organizations for health insurance coverage offered in such State in connection with a group health plan;

"(3) such tax is otherwise nondiscriminatory; and

"(4) the amount of any such tax assessed on the plan is reduced by the amount of any tax or assessment otherwise imposed by the State on premiums, contributions, or both received by insurers or health maintenance organizations for health insurance coverage, aggregate excess/stop loss insurance (as defined in section 806(g)(1)), specific excess/stop loss insurance (as defined in section 806(g)(2)), other insurance related to the provision of medical care under the plan, or any combination thereof provided by such insurers or health maintenance organizations in such State in connection with such plan.

"SEC. 812. DEFINITIONS AND RULES OF CONSTRUCTION.

"(a) DEFINITIONS.—For purposes of this part—

"(1) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning provided in section 733(a)(1) (after applying subsection (b) of this section).

"(2) MEDICAL CARE.—The term 'medical care' has the meaning provided in section 733(a)(2).

"(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning provided in section 733(b)(1).

"(4) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning provided in section 733(b)(2).

"(5) APPLICABLE AUTHORITY.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'applicable authority' means, in connection with an association health plan—

"(i) the State recognized pursuant to subsection (c) of section 506 as the State to which authority has been delegated in connection with such plan; or

"(ii) if there if no State referred to in clause (i), the Secretary.

"(B) EXCEPTIONS.—

"(i) JOINT AUTHORITIES.—Where such term appears in section 808(3), section 807(e) (in the first instance), section 809(a) (in the second instance), section 809(a) (in the fourth instance), and section 809(b)(1), such term means, in connection with an association health plan, the Secretary and the State referred to in subparagraph (A)(i) (if any) in connection with such plan.

"(ii) REGULATORY AUTHORITIES.—Where such term appears in section 802(a) (in the first instance), section 802(d), section 802(e), section 803(d), section 805(a)(5), section 806(a)(2), section 806(b), section 806(c), section 806(d), paragraphs (1)(A) and (2)(A) of section 806(g), section 806(h), section 806(i), section 806(j), section 807(a) (in the second instance), section 807(b), section 807(d), section 807(e) (in the second instance), section 808 (in the matter after paragraph (3)), and section 809(a) (in the third instance), such term means, in connection with an association health plan, the Secretary.

"(6) HEALTH STATUS-RELATED FACTOR.—The term 'health status-related factor' has the meaning provided in section 733(d)(2).

"(7) INDIVIDUAL MARKET.—

"(A) IN GENERAL.—The term 'individual market' means the market for health insurance coverage offered

to individuals other than in connection with a group health plan.

"(B) TREATMENT OF VERY SMALL GROUPS.—

"(i) IN GENERAL.—Subject to clause (ii), such term includes coverage offered in connection with a group health plan that has fewer than 2 participants as current employees or participants described in section 732(d)(3) on the first day of the plan year.

"(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of health insurance coverage offered in a State if such State regulates the coverage described in such clause in the same manner and to the same extent as coverage in the small group market (as defined in section 2791(e)(5) of the Public Health Service Act) is regulated by such State.

"(8) PARTICIPATING EMPLOYER.—The term 'participating employer' means, in connection with an association health plan, any employer, if any individual who is an employee of such employer, a partner in such employer, or a self-employed individual who is such employer (or any dependent, as defined under the terms of the plan, of such individual) is or was covered under such plan in connection with the status of such individual as such an employee, partner, or self-employed individual in relation to the plan.

"(9) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of title XXVII of the Public Health Service Act for the State involved with respect to such issuer.

"(10) QUALIFIED ACTUARY.—The term 'qualified actuary' means an individual who is a member of the American Academy of Actuaries or meets such reasonable standards and qualifications as the Secretary may provide by regulation through negotiated rulemaking.

"(11) AFFILIATED MEMBER.—The term 'affiliated member' means, in connection with a sponsor—

"(A) a person who is otherwise eligible to be a member of the sponsor but who elects an affiliated status with the sponsor,

"(B) in the case of a sponsor with members which consist of associations, a person who is a member of any such association and elects an affiliated status with the sponsor, or

"(C) in the case of an association health plan in existence on the date of the enactment of the Patients' Bill of Rights Act of 2001, a person eligible to be a member of the sponsor or one of its member associations.

"(12) LARGE EMPLOYER.—The term 'large employer' means, in connection with a group health plan with respect to a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

"(13) SMALL EMPLOYER.—The term 'small employer' means, in connection with a group health plan with respect to a plan year, an employer who is not a large employer.

"(b) RULES OF CONSTRUCTION.—

"(1) EMPLOYERS AND EMPLOYEES.—For purposes of determining whether a plan, fund, or program is an employee welfare benefit plan which is an association health plan, and for purposes of applying this title in connection with such plan, fund, or program so determined to be such an employee welfare benefit plan—

"(A) in the case of a partnership, the term 'employer' (as defined in section 3(5)) includes the partnership in relation to the partners, and the term 'employee' (as defined in section 3(6)) includes any partner in relation to the partnership; and

"(B) in the case of a self-employed individual, the term 'employer' (as defined in section 3(5)) and the

term 'employee' (as defined in section 3(6)) shall include such individual.

''(2) PLANS, FUNDS, AND PROGRAMS TREATED AS EMPLOYEE WELFARE BENEFIT PLANS.—In the case of any plan, fund, or program which was established or is maintained for the purpose of providing medical care (through the purchase of insurance or otherwise) for employees (or their dependents) covered thereunder and which demonstrates to the Secretary that all requirements for certification under this part would be met with respect to such plan, fund, or program if such plan, fund, or program were a group health plan, such plan, fund, or program shall be treated for purposes of this title as an employee welfare benefit plan on and after the date of such demonstration.''.

(b) CONFORMING AMENDMENTS TO PREEMPTION RULES.—

(1) Section 514(b)(6) of such Act (29 U.S.C. 1144(b)(6)) is amended by adding at the end the following new subparagraph:

''(E) The preceding subparagraphs of this paragraph do not apply with respect to any State law in the case of an association health plan which is certified under part 8.''.

(2) Section 514 of such Act (29 U.S.C. 1144), as amended by section 142, is amended—

(A) in subsection (b)(4), by striking ''Subsection (a)'' and inserting ''Subsections (a) and (e)'';

(B) in subsection (b)(5), by striking ''subsection (a)'' in subparagraph (A) and inserting ''subsection (a) of this section and subsections (a)(2)(B) and (b) of section 805'', and by striking ''subsection (a)'' in subparagraph (B) and inserting ''subsection (a) of this section or subsection (a)(2)(B) or (b) of section 805'';

(C) by redesignating subsection (e) as subsection (f); and

(D) by inserting after subsection (d) the following new subsection:

''(e)(1) Except as provided in subsection (b)(4), the provisions of this title shall supersede any and all State laws insofar as they may now or hereafter preclude, or have the effect of precluding, a health insurance issuer from offering health insurance coverage in connection with an association health plan which is certified under part 8.

''(2) Except as provided in paragraphs (4) and (5) of subsection (b) of this section—

''(A) In any case in which health insurance coverage of any policy type is offered under an association health plan certified under part 8 to a participating employer operating in such State, the provisions of this title shall supersede any and all laws of such State insofar as they may preclude a health insurance issuer from offering health insurance coverage of the same policy type to other employers operating in the State which are eligible for coverage under such association health plan, whether or not such other employers are participating employers in such plan.

''(B) In any case in which health insurance coverage of any policy type is offered under an association health plan in a State and the filing, with the applicable State authority, of the policy form in connection with such policy type is approved by such State authority, the provisions of this title shall supersede any and all laws of any other State in which health insurance coverage of such type is offered, insofar as they may preclude, upon the filing in the same form and manner of such policy form with the applicable State authority in such other State, the approval of the filing in such other State.

''(3) For additional provisions relating to association health plans, see subsections (a)(2)(B) and (b) of section 805.

''(4) For purposes of this subsection, the term 'association health plan' has the meaning provided in section 801(a), and the terms 'health insurance coverage', 'participating employer', and 'health insurance issuer' have the meanings provided such terms in section 811, respectively.''.

(3) Section 514(b)(6)(A) of such Act (29 U.S.C. 1144(b)(6)(A)) is amended—

(A) in clause (i)(II), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and which does not provide medical care (within the meaning of section 733(a)(2)),'' after ''arrangement,'', and by striking ''title.'' and inserting ''title, and''; and

(C) by adding at the end the following new clause:

''(iii) subject to subparagraph (E), in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement and which provides medical care (within the meaning of section 733(a)(2)), any law of any State which regulates insurance may apply.''.

(4) Section 514(e) of such Act (as redesignated by paragraph (2)(C)) is amended—

(A) by striking ''Nothing'' and inserting ''(1) Except as provided in paragraph (2), nothing''; and

(B) by adding at the end the following new paragraph:

''(2) Nothing in any other provision of law enacted on or after the date of the enactment of the Patients' Bill of Rights Act of 2001 shall be construed to alter, amend, modify, invalidate, impair, or supersede any provision of this title, except by specific cross-reference to the affected section.''.

(c) PLAN SPONSOR.—Section 3(16)(B) of such Act (29 U.S.C. 102(16)(B)) is amended by adding at the end the following new sentence: ''Such term also includes a person serving as the sponsor of an association health plan under part 8.''.

(d) DISCLOSURE OF SOLVENCY PROTECTIONS RELATED TO SELF-INSURED AND FULLY INSURED OPTIONS UNDER ASSOCIATION HEALTH PLANS.—Section 102(b) of such Act (29 U.S.C. 102(b)) is amended by adding at the end the following: ''An association health plan shall include in its summary plan description, in connection with each benefit option, a description of the form of solvency or guarantee fund protection secured pursuant to this Act or applicable State law, if any.''.

(e) SAVINGS CLAUSE.—Section 731(c) of such Act is amended by inserting ''or part 8'' after ''this part''.

(f) REPORT TO THE CONGRESS REGARDING CERTIFICATION OF SELF-INSURED ASSOCIATION HEALTH PLANS.—Not later than January 1, 2006, the Secretary of Labor shall report to the Committee on Education and the Workforce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate the effect association health plans have had, if any, on reducing the number of uninsured individuals.

(g) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 734 the following new items:

''PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

''Sec. 801. Association health plans.
''Sec. 802. Certification of association health plans.
''Sec. 803. Requirements relating to sponsors and boards of trustees.
''Sec. 804. Participation and coverage requirements.
''Sec. 805. Other requirements relating to plan documents, contribution rates, and benefit options.
''Sec. 806. Maintenance of reserves and provisions for solvency for plans providing health benefits in addition to health insurance coverage.
''Sec. 807. Requirements for application and related requirements.
''Sec. 808. Notice requirements for voluntary termination.
''Sec. 809. Corrective actions and mandatory termination.
''Sec. 810. Trusteeship by the Secretary of insolvent association health plans providing health benefits in addition to health insurance coverage.
''Sec. 811. State assessment authority.
''Sec. 812. Definitions and rules of construction.''.

SEC. 622. CLARIFICATION OF TREATMENT OF SINGLE EMPLOYER ARRANGEMENTS.

Section 3(40)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(40)(B)) is amended—

(1) in clause (i), by inserting ''for any plan year of any such plan, or any fiscal year of any such other arrangement;'' after ''single employer'', and by inserting ''during such year or at any time during the preceding 1-year period'' after ''control group'';

(2) in clause (iii)—

(A) by striking ''common control shall not be based on an interest of less than 25 percent'' and inserting ''an interest of greater than 25 percent may not be required as the minimum interest necessary for common control''; and

(B) by striking ''similar to'' and inserting ''consistent and coextensive with'';

(3) by redesignating clauses (iv) and (v) as clauses (v) and (vi), respectively; and

(4) by inserting after clause (iii) the following new clause:

''(iv) in determining, after the application of clause (i), whether benefits are provided to employees of two or more employers, the arrangement shall be treated as having only one participating employer if, after the application of clause (i), the number of individuals who are employees and former employees of any one participating employer and who are covered under the arrangement is greater than 75 percent of the aggregate number of all individuals who are employees or former employees of participating employers and who are covered under the arrangement;''.

SEC. 623. CLARIFICATION OF TREATMENT OF CERTAIN COLLECTIVELY BARGAINED ARRANGEMENTS.

(a) IN GENERAL.—Section 3(40)(A)(i) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(40)(A)(i)) is amended to read as follows:

''(i)(I) under or pursuant to one or more collective bargaining agreements which are reached pursuant to collective bargaining described in section 8(d) of the National Labor Relations Act (29 U.S.C. 158(d)) or paragraph Fourth of section 2 of the Railway Labor Act (45 U.S.C. 152, paragraph Fourth) or which are reached pursuant to labor-management negotiations under similar provisions of State public employee relations laws, and (II) in accordance with subparagraphs (C), (D), and (E);''.

(b) LIMITATIONS.—Section 3(40) of such Act (29 U.S.C. 1002(40)) is amended by adding at the end the following new subparagraphs:

"(C) For purposes of subparagraph (A)(i)(II), a plan or other arrangement shall be treated as established or maintained in accordance with this subparagraph only if the following requirements are met:

"(i) The plan or other arrangement, and the employee organization or any other entity sponsoring the plan or other arrangement, do not—

"(I) utilize the services of any licensed insurance agent or broker for soliciting or enrolling employers or individuals as participating employers or covered individuals under the plan or other arrangement; or

"(II) pay any type of compensation to a person, other than a full time employee of the employee organization (or a member of the organization to the extent provided in regulations prescribed by the Secretary through negotiated rulemaking), that is related either to the volume or number of employers or individuals solicited or enrolled as participating employers or covered individuals under the plan or other arrangement, or to the dollar amount or size of the contributions made by participating employers or covered individuals to the plan or other arrangement;

except to the extent that the services used by the plan, arrangement, organization, or other entity consist solely of preparation of documents necessary for compliance with the reporting and disclosure requirements of part 1 or administrative, investment, or consulting services unrelated to solicitation or enrollment of covered individuals.

"(ii) As of the end of the preceding plan year, the number of covered individuals under the plan or other arrangement who are neither—

"(I) employed within a bargaining unit covered by any of the collective bargaining agreements with a par-

ticipating employer (nor covered on the basis of an individual's employment in such a bargaining unit); nor

"(II) present employees (or former employees who were covered while employed) of the sponsoring employee organization, of an employer who is or was a party to any of the collective bargaining agreements, or of the plan or other arrangement or a related plan or arrangement (nor covered on the basis of such present or former employment);

does not exceed 15 percent of the total number of individuals who are covered under the plan or arrangement and who are present or former employees who are or were covered under the plan or arrangement pursuant to a collective bargaining agreement with a participating employer. The requirements of the preceding provisions of this clause shall be treated as satisfied if, as of the end of the preceding plan year, such covered individuals are comprised solely of individuals who were covered individuals under the plan or other arrangement as of the date of the enactment of the Patients' Bill of Rights Act of 2001 and, as of the end of the preceding plan year, the number of such covered individuals does not exceed 25 percent of the total number of present and former employees enrolled under the plan or other arrangement.

"(iii) The employee organization or other entity sponsoring the plan or other arrangement certifies to the Secretary each year, in a form and manner which shall be prescribed by the Secretary through negotiated rulemaking that the plan or other arrangement meets the requirements of clauses (i) and (ii).

"(D) For purposes of subparagraph (A)(i)(II), a plan or arrangement shall be treated as established or maintained in accordance with this subparagraph only if—

"(i) all of the benefits provided under the plan or arrangement consist of health insurance coverage; or

"(ii)(I) the plan or arrangement is a multiemployer plan; and

"(II) the requirements of clause (B) of the proviso to clause (5) of section 302(c) of the Labor Management Relations Act, 1947 (29 U.S.C. 186(c)) are met with respect to such plan or other arrangement.

"(E) For purposes of subparagraph (A)(i)(II), a plan or arrangement shall be treated as established or maintained in accordance with this subparagraph only if—

"(i) the plan or arrangement is in effect as of the date of the enactment of the Patients' Bill of Rights Act of 2001; or

"(ii) the employee organization or other entity sponsoring the plan or arrangement—

"(I) has been in existence for at least 3 years; or

"(II) demonstrates to the satisfaction of the Secretary that the requirements of subparagraphs (C) and (D) are met with respect to the plan or other arrangement.".

(c) CONFORMING AMENDMENTS TO DEFINITIONS OF PARTICIPANT AND BENEFICIARY.—Section 3(7) of such Act (29 U.S.C. 1002(7)) is amended by adding at the end the following new sentence: "Such term includes an individual who is a covered individual described in paragraph (40)(C)(ii).".

SEC. 624. ENFORCEMENT PROVISIONS RELATING TO ASSOCIATION HEALTH PLANS.

(a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL MISREPRESENTATIONS.—Section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131) is amended—

(1) by inserting "(a)" after "SEC. 501."; and

(2) by adding at the end the following new subsection:

"(b) Any person who willfully falsely represents, to any employee, any employee's beneficiary, any employer, the Secretary, or any State, a plan or other arrangement established or maintained for the purpose of offering or providing any benefit described in section 3(1) to employees or their beneficiaries as—

"(1) being an association health plan which has been certified under part 8;

"(2) having been established or maintained under or pursuant to one or more collective bargaining agreements which are reached pursuant to collective bargaining described in section 8(d) of the National Labor Relations Act (29 U.S.C. 158(d)) or paragraph Fourth of section 2 of the Railway Labor Act (45 U.S.C. 152, paragraph Fourth) or which are reached pursuant to labor-management negotiations under similar provisions of State public employee relations laws; or

"(3) being a plan or arrangement with respect to which the requirements of subparagraph (C), (D), or (E) of section 3(40) are met;

shall, upon conviction, be imprisoned not more than 5 years, be fined under title 18, United States Code, or both.".

(b) CEASE ACTIVITIES ORDERS.—Section 502 of such Act (29 U.S.C. 1132), as amended by sections 141 and 143, is further amended by adding at the end the following new subsection:

"(p) ASSOCIATION HEALTH PLAN CEASE AND DESIST ORDERS.—

"(1) IN GENERAL.—Subject to paragraph (2), upon application by the Secretary showing the operation, promotion, or marketing of an association health plan (or similar arrangement providing benefits consisting of medical care (as defined in section 733(a)(2))) that—

"(A) is not certified under part 8, is subject under section 514(b)(6) to the insurance laws of any State in which the plan or arrangement offers or provides benefits, and is not licensed, registered, or otherwise approved under the insurance laws of such State; or

"(B) is an association health plan certified under part 8 and is not operating in accordance with the requirements under part 8 for such certification,

a district court of the United States shall enter an order requiring that the plan or arrangement cease activities.

''(2) EXCEPTION.—Paragraph (1) shall not apply in the case of an association health plan or other arrangement if the plan or arrangement shows that—

''(A) all benefits under it referred to in paragraph (1) consist of health insurance coverage; and

''(B) with respect to each State in which the plan or arrangement offers or provides benefits, the plan or arrangement is operating in accordance with applicable State laws that are not superseded under section 514.

''(3) ADDITIONAL EQUITABLE RELIEF.—The court may grant such additional equitable relief, including any relief available under this title, as it deems necessary to protect the interests of the public and of persons having claims for benefits against the plan.''.

(c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—Section 503 of such Act (29 U.S.C. 1133), as amended by section 301(b), is amended by adding at the end the following new subsection:

''(c) ASSOCIATION HEALTH PLANS.—The terms of each association health plan which is or has been certified under part 8 shall require the board of trustees or the named fiduciary (as applicable) to ensure that the requirements of this section are met in connection with claims filed under the plan.''.

SEC. 625. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Section 506 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1136) is amended by adding at the end the following new subsection:

''(c) CONSULTATION WITH STATES WITH RESPECT TO ASSOCIATION HEALTH PLANS.—

''(1) AGREEMENTS WITH STATES.—The Secretary shall consult with the State recognized under paragraph (2) with respect to an association health plan regarding the exercise of—

''(A) the Secretary's authority under sections 502 and 504 to enforce the requirements for certification under part 8; and

''(B) the Secretary's authority to certify association health plans under part 8 in accordance with regulations of the Secretary applicable to certification under part 8.

''(2) RECOGNITION OF PRIMARY DOMICILE STATE.—In carrying out paragraph (1), the Secretary shall ensure that only one State will be recognized, with respect to any particular association health plan, as the State to with which consultation is required. In carrying out this paragraph, the Secretary shall take into account the places of residence of the participants and beneficiaries under the plan and the State in which the trust is maintained.''.

SEC. 626. EFFECTIVE DATE AND TRANSITIONAL AND OTHER RULES.

(a) EFFECTIVE DATE.—The amendments made by sections 621, 624, and 625 shall take effect one year from the date of enactment. The amendments made by sections 622 and 623 shall take effect on the date of the enactment of this Act. The Secretary of Labor shall first issue all regulations necessary to carry out the amendments made by this subtitle within one year from the date of enactment. Such regulations shall be issued through negotiated rulemaking.

(b) EXCEPTION.—Section 801(a)(2) of the Employee Retirement Income Security Act of 1974 (added by section 621) does not apply in connection with an association health plan (certified under part 8 of subtitle B of title I of such Act) existing on the date of the enactment of this Act, if no benefits provided thereunder as of the date of the enactment of this Act consist of health insurance coverage (as defined in section 733(b)(1) of such Act).

(c) TREATMENT OF CERTAIN EXISTING HEALTH BENEFITS PROGRAMS.—

(1) IN GENERAL.—In any case in which, as of the date of the enactment of this Act, an arrangement is maintained

in a State for the purpose of providing benefits consisting of medical care for the employees and beneficiaries of its participating employers, at least 200 participating employers make contributions to such arrangement, such arrangement has been in existence for at least 10 years, and such arrangement is licensed under the laws of one or more States to provide such benefits to its participating employers, upon the filing with the applicable authority (as defined in section 812(a)(5) of the Employee Retirement Income Security Act of 1974 (as amended by this subtitle)) by the arrangement of an application for certification of the arrangement under part 8 of subtitle B of title I of such Act—

(A) such arrangement shall be deemed to be a group health plan for purposes of title I of such Act;

(B) the requirements of sections 801(a)(1) and 803(a)(1) of the Employee Retirement Income Security Act of 1974 shall be deemed met with respect to such arrangement;

(C) the requirements of section 803(b) of such Act shall be deemed met, if the arrangement is operated by a board of directors which—

(i) is elected by the participating employers, with each employer having one vote; and

(ii) has complete fiscal control over the arrangement and which is responsible for all operations of the arrangement;

(D) the requirements of section 804(a) of such Act shall be deemed met with respect to such arrangement; and

(E) the arrangement may be certified by any applicable authority with respect to its operations in any State only if it operates in such State on the date of certification.

The provisions of this subsection shall cease to apply with respect to any such arrangement at such time after the date of the enactment of this Act as the applicable require-

ments of this subsection are not met with respect to such arrangement.

(2) DEFINITIONS.—For purposes of this subsection, the terms ''group health plan'', ''medical care'', and ''participating employer'' shall have the meanings provided in section 812 of the Employee Retirement Income Security Act of 1974, except that the reference in paragraph (7) of such section to an ''association health plan'' shall be deemed a reference to an arrangement referred to in this subsection.